UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	May 17, 2018
Doris Jones, an individual,	1:00 p.m.
Plaintiff,	
	CV 16-00782-PHX-DGC
vs.	
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(*Jury Trial - Day 3 - P.M. Session*)
(*Pages 591 through 719, inclusive.*)

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I N D E X

EXHIBIT	RECEIVED
755	655
770	705
1613	625
1149	622
1219	670
1578	690
1219	670
1616	701
2248	684
4409	696
4430	702
4433	704
4438	699
4554	632

P R O C E E D I N G S

THE COURT: Counsel, you may continue.

MR. LOPEZ: Plaintiffs will call Mr. Rob Carr.

THE COURT: All right.

THE COURTROOM DEPUTY: Mr. Carr, please come forward. Raise your right hand, sir. 01:00PM

(The witness was sworn.)

MR. LOPEZ: May I proceed, Your Honor? Thank you.

ROB CARR,

called as a witness herein, having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. LOPEZ:

Q. Good afternoon, Mr. Carr. Thank you for being here.

A. Good afternoon. 01:01PM

Q. You are currently employed by Bard?

A. Yes, I am.

Q. And would it be the Bard Peripheral Vascular Division of C.R. Bard?

A. Yes. 01:01PM

Q. What's your current title or position there?

A. I'm the vice president of international.

Q. What does that mean?

A. It means that I support all of our business outside of the United States. 01:01PM

Q. When you say support all of your business, is that -- why don't you just explain to the jury what that means when you say you support all of your business outside the United States.
A. So I literally support all aspects of the business for our division outside of America, be that physician training, sales training, supply, some marketing, some R&D technical questions, so me and my group support that. 01:01PM
Q. So I have just not the word "support" before as a -- does that mean that you work for somebody who gives you direction to then give support to other people that are in your international division? 01:02PM
A. So the way our business is structured, commercially, those, let's take China, the people who work in China don't report to me so I support their commercial side of their business.
Q. Okay. So in other words, your position is basically commercial or marketing at this point? 01:02PM
A. No, it's more than that. It's like I described, all of the above.
Q. Do you have any engineering functions currently at Bard where you are actually doing engineering type of activities? 01:02PM
A. Again, only to answer questions or technical things that someone might have.
Q. Okay. Now, is it true that there's probably no one at Bard that has been more involved in the aspect of Bard IVC filters than Rob Carr? 01:03PM

A. As a general statement I think that's probably true.
Q. And I think you told us a while back that you know more about Bard IVC filters than anyone else in the company. Is that true?
A. I don't know if I said that. I think others have. 01:03PM
Q. Now, in fact, you have had your deposition taken 10, 11, 12 times in this litigation, is that right? Do you remember that?
A. I don't know how many. Several.
Q. And you know that you have been designated a number of times by Bard or its lawyers to testify as a person most 01:03PM knowledgeable or most qualified on a number of Bard IVC filter related topics. True?
A. Yes.
Q. You have been designated to be that person most knowledgeable to discuss risks, complications in sales. True? 01:04PM
A. I don't know specifically.
Q. Do you want to look at -- do we need to look at your depositions to remind you about that?
A. Yes, please.
Q. Well, let me ask you, can we look at 730, then, Exhibit 01:04PM 730? That's the deposition notice. That was -- I'm sorry it's a deposition taken April 17, 2003. I'm sorry, 2013.
Does this refresh your recollection that your deposition was taken as a person most knowledgeable on that date? Is there a next page to this? Keep going. That lists 01:05PM

the subject matter. Keep going. There we go.

MR. LOPEZ: Can I admit this, Your Honor, and publish it to the jury as a deposition notice? This is a deposition of subject matter.

MR. NORTH: Objection 402 and 403 and in violation of the Court's ruling on Motion in Limine./HRO*P /HROP I don't think this page is, Your Honor. 01:05PM

THE COURT: Sustained.

BY MR. LOPEZ:

Q. Okay. Mr. Carr, you were designated as a person most knowledgeable to discuss risks and complications associated with the Recovery, G2, G2 Express Filters in a deposition taken April 17, 2013. True? 01:05PM

A. I don't know the exact reasons.

Q. Look at the screen. 01:05PM

A. Oh. Yes.

Q. And you were also designated to be a person most knowledgeable to talk about the sales brochure for G2 filters. Do you recall that -- it's not on this. Don't look at the screen -- at another deposition? 01:06PM

A. Again, you would have to -- I don't know the specific reasons.

Q. Well, two months ago I asked you this question: Were you designated as a person most knowledgeable to testify about Bard's sales brochures for the G2 Filter? Do you remember 01:06PM

that?

MR. NORTH: Objection, Your Honor 402.

THE COURT: Overruled.

THE WITNESS: Not specifically, no.

BY MR. LOPEZ: 01:06PM

Q. Well, let me ask you, sir, prior to your coming here to today to testify, did you prepare yourself to testify?

A. Yes.

Q. I mean, did you prepare yourself to look at your history of your involvement in giving depositions so you could give the 01:06PM jury the best testimony that you possibly could today and the most truthful testimony?

A. I didn't read every document, if that's what you are asking me. But yes, I prepared.

Q. And as part of that preparation, you didn't look at any of 01:07PM the prior depositions that you have given in this litigation?

A. I didn't say that.

Q. Did you look at the deposition that you took -- I mean that was taken on October 29, 2014?

A. I don't know. 01:07PM

Q. And were you a person most knowledgeable at that deposition on the sales brochure for the G2 Filter?

A. I don't know.

Q. Let's look at 753, please. That's the deposition taken on 10-29-2014. 01:07PM

MR. LOPEZ: Go to the page that describes the subject matter for which Mr. Carr was designated as a person most knowledgeable since he doesn't remember. There we go. Keep going one more.

BY MR. LOPEZ: 01:08PM

Q. Sir, this deposition was taken on October 29, 2014, just to refresh your recollection. Does this help refresh your recollection about the subject matter for which you were being deposed on that day?

A. Yes. But I don't see those words on this page. 01:08PM

Q. Can we go to the exhibit that's attached?

Okay. This is the G2 brochure?

A. Yes.

Q. And you really don't remember that you were designated as a person to talk about the sales material as they relate to the 01:09PM Recovery and G2 Filter three years ago?

A. As you said, I have been deposed many times.

Q. All right. Let's see if you and I can agree on some things.

The Recovery, the G2, the G2 Express, as well as the 01:09PM Eclipse and any other so-called retrievable device that is being marketed by Bard should perform as well as permanent filters. True?

A. They perform differently than permanent filters, so not in every case, no. 01:10PM

Q. But they should perform as well from the patient's safety standpoint, should they not?
A. They must be safe and effective, yes.
MR. LOPEZ: Can we go to Mr. Carr's deposition November 5, 2013, beginning at Page 41, Line 11. I'm sorry. October 25, 2013, Page 41. 01:10PM
BY MR. LOPEZ:
Q. Do you have it in front of you, sir?
A. Yes.
Q. Okay. This must be the wrong deposition. Is this 11-5-13 or 11-25-13? 01:11PM
(Discussion off the record.)
BY MR. LOPEZ:
Q. There we go. Okay. Sir, see the deposition in front of you, Line 11? 01:12PM
A. Yes.
Q. You were asked this question: Sir, would you agree that optional filters, the Recovery, the G2, the G2 Express should perform as well as permanent filters? And your answer was yes. Do you see that? 01:12PM
A. Yes.
Q. Now we go to 41, same deposition, 41:19, I'm going to ask you the same question. The Recovery era, the G2 era and the G2 Express, did Bard have a truly permanent filter that was commercially available? And your answer is: All of them are 01:12PM

truly permanent. Right?
A. Yes.
Q. So when we talk about Bard retrievable filters, they are permanent filters?
A. Some are only permanent and some are optionally removed. 01:13PM
Q. Right. But as a permanent filter, they should be as safe and effective as any other permanent filter on the market, in particular, its predicate device the Simon Nitinol Filter. True?
A. No. Different filters have different advantages and 01:13PM disadvantages so not as -- they should all be safe and effective.
Q. Let me ask you, shouldn't the Bard filters perform at least as well from a safety and effectiveness standpoint and as the Simon Nitinol Filter? 01:13PM
A. They should all meet their specification which shows that they are both safe and effective.
Q. Can we go to Page 44, Line 14 of the same deposition.
Sir, you were asked: So shouldn't the G2 still perform as well as the Simon Nitinol Filter? On that day you 01:13PM gave me a simple answer which was yes. True?
A. Yes.
Q. Now, you don't sacrifice safety when you design a filter to have a retrievable option, do you?
A. No. Again, all of our devices are both safe and effective. 01:14PM

Q. I didn't ask you that question. I asked you -- Mr. North, in his opening statement, seemed to indicate that it was a little bit more difficult to design an optional filter. You had to make some compromises. Would you agree that you don't make compromises to make a device retrievable in the area of safety? 01:14PM

A. No. Again, they are all safe and effective.

Q. Would you agree that stability and integrity of the filter should not be different whether or not it's being implanted in a patient to be there permanently or potentially to be removed later? 01:14PM

A. I'm sorry. Could you say that again?

Q. Well, you know what the word stability means as relates to an IVC filter?

A. Stability? Yes. 01:15PM

Q. In fact, it's on one of your brochures. You brag about how the G2 has taken stability to a new level, correct?

A. First of all, we don't brag about anything.

Q. Well, stability is an important word when it comes to the safety of IVC filters. You would agree with me, wouldn't you? 01:15PM

A. I would.

Q. And integrity, do you know what integrity means as it relates to a filter?

A. I do.

Q. What does integrity mean? 01:15PM

A. It means that it stays together.
Q. So it shouldn't break and should stay where you put it. That's the purpose. That's the idea in designing an IVC filter. Correct?
A. That is the goal, yes. 01:15PM
Q. And that stability, that integrity, should not be different whether or not the device is being implanted to stay in permanently or implanted to potentially be taken out later. True?
A. Again, they are all -- 01:15PM
Q. Sir, is that true or not?
A. No, it's not.
Q. So they can have different stability and integrities depending upon whether or not it's left in permanently or comes out, say, sometime after it's implanted? Is that what you are 01:16PM telling the jury?
A. Yes. I'm saying that they have different performance specifications that all show that they are both safe and effective.
Q. So when you were selling the Eclipse Filter, the G2 Filter, 01:16PM the Recovery Filter, were you telling doctors that if you are going to leave this in permanently it has a different safety profile than if you take it out after a certain period of time? Yes or no?
A. No. 01:16PM

Q. You were telling them that the G2, the Eclipse would perform safely and effectively whether or not you were putting it in short-term or whether or not you were going to leave it in for the life of the patient. True?
A. Yes, and it does. 01:16PM
Q. Other than the Asch pilot study that we heard some testimony about yesterday for retrievability of the Recovery Filter, and the EVEREST trial for retrievability of the G2 Filter, there has been no Recovery, G2, G2X, G2 Express, or Eclipse Filter that has undergone a controlled clinical trial 01:17PM where patients are enrolled and monitored. True?
A. Other than those two, no.
Q. There has never been a long term monitored and controlled clinical trial of any Bard filter from Recovery to and including Eclipse specifically designed to determine safe 01:17PM retrievability beyond 180 days. True?
A. Not beyond 180 days. But the time period is very long.
Q. And there never been a long term monitored or controlled clinical trial of any Bard filter, up to and including Eclipse, specifically to determine long term safety and effectiveness as 01:17PM a permanent device. True?
A. Not past 180 days, no.
Q. The Asch study provided data for retrieval in less than 50 patients with an average time to retrieval of 53 days. True?
A. I don't know. 01:18PM

Q. You don't know anything about the Asch study?
A. I know a lot about the Asch study --
Q. Not about that aspect --
MR. NORTH: Your Honor, could he allow the witness.
THE COURT: Would you please let the witness answer before you interrupt, Mr. Lopez. 01:18PM
MR. LOPEZ: Sorry.
THE WITNESS: I know a lot about the Asch study. I just don't know exact numbers.
BY MR. LOPEZ: 01:18PM
Q. And EVEREST provided data for retrieval in less than 50 patients with an average time of retrieval of 140 days. True?
A. Again, I don't know those numbers, no.
Q. Would you agree with -- do you know who Mr. Chris Ganser is? 01:18PM
A. Yes.
Q. Who is Mr. Chris Ganser?
A. He was a -- I don't know his exact title but he was a head of quality.
Q. He was head of quality at the corporate level at C.R. Bard. 01:18PM True?
A. Yes.
Q. He would have been someone that would have had on the hierarchy a very high position, very close to the president and CEO. True? 01:19PM

A. I don't know who he reported to, but he worked at the corporate office.
Q. Would you agree with Mr. Ganser if he said that transparency in matters that affect patients' safety should be embraced as a primary corporate obligation. Do you agree with that? 01:19PM
A. I do.
Q. Now, the ultimate decision about -- would you agree with this, sir: That the ultimate decision about the acceptability of inherent risks associated with Bard IVC filter rests with the patient who is going to receive the filter? 01:19PM
A. I don't know that. I think it might be the doctor.
Q. You think -- you are not familiar with the informed consent requirement before one of your medical devices can be implanted in a patient? 01:19PM
A. Yes.
Q. You know that ultimately, the person who needs to make the decision about whether or not to implant something in their body that's potentially dangerous is the patient?
A. I don't know. I think I listen to my doctors, so I'm not -- 01:20PM
Q. I know. But the decision, I'm talking about. I mean --
A. Yes. They sign a consent.
Q. Thank you. Your wife is a doctor, right?
A. My wife is an immunologist. 01:20PM

Q. And you know about informed consent, right?
A. No, she doesn't practice.
Q. When she was practicing she just couldn't treat patients and give them whatever she wanted to give them. She had to have an informed consent discussion with them and give her all the various options of treatment and the patient had to say yes. True? 01:20PM
A. No. My wife never practiced.
Q. Okay. But you know that as being married to a doctor that that's how it works in the real world, that patients are the ones who have to be informed and be provided with information so that they can make the decision on whether or not they want something implanted in their body. Right? 01:20PM
A. I know that patients sign consents.
Q. And certainly people at Bard, the marketing department, the sales department, and other departments shouldn't be making decisions on behalf of people like Doris Jones as to whether or not the risks of your devices are acceptable to her. True? 01:21PM
A. No, I don't believe that.
Q. You don't believe what? 01:21PM
A. That we don't make those determinations.
Q. You shouldn't?
THE COURT: Are you saying should or should not?
BY MR. LOPEZ:
Q. Bard should not be making decisions about acceptability, 01:21PM

about risks that are acceptable to patients like Doris Jones. Do you agree with that?
A. No, I don't. I don't understand your question maybe.
Q. Maybe you don't.
Will you agree with this, sir, that patients are entitled to receive full disclosure of all material information that Bard possesses about safety, performance, design deficiencies, and complications in order to make informed decisions about whether or not to consent to the insertion of a Bard IVC filter in their body. Do you agree or disagree with that? 01:22PM
A. I don't think I agree with that fully, no.
Q. Sir, do you agree that it is a reasonable expectation of doctors and patients that they treat that medical device companies provide honest, accurate, and updated information about the safety and effectiveness of its potentially dangerous products to allow doctors to fulfill their obligation of informed consent to the patient? 01:22PM
A. Yes, and we do.
Q. In order for a physician caring for patients who are candidates for IVC filters to provide their patients with appropriate informed consent, the companies who manufacture, market, and profit from these devices must provide current and up-to-date information about the frequency, severity, and type of complications associated with their specific filter. Do you 01:22PM 01:23PM

agree with that, sir?
A. No, I don't.
Q. Do you agree that the experiences of other physicians with the use of potentially dangerous medical devices like IVC filters, especially new devices, and particularly when there's 01:23PM
no controlled clinical trial that exists that provides data for long term safety and effectiveness is important information to share with other doctors?
A. But there is clinical trial data.
Q. I said long term safety and effectiveness information. 01:23PM
A. There is long term safety and effectiveness.
Q. And where did you get that?
A. From the EVEREST trial.
Q. I'm sorry?
A. EVEREST trial. 01:23PM
Q. The EVEREST trial where you follow a patient for 180 days and didn't follow them after? That's the long term study that you did?
A. Yes.
Q. That's long term? 01:24PM
A. Yes.
Q. And so that's a study where I think about a third of the people went on and weren't followed and Bard knows nothing about what happened to those people and you consider that a long term safety and effectiveness study. True? 01:24PM

A. Yes. All trials have an end point.
Q. I understand. But that study, sir, the purpose of that study -- and the study was designed to determine whether or not a G2 Filter can be retrieved within 180 days. True?
A. Among other things. 01:24PM
Q. But, sir, that part of it was true. Right?
A. Yes.
Q. It wasn't designed to follow patients after 180 days. True?
A. That's correct. 01:24PM
Q. So you know nothing about what happened to patients like Ms. Jones who had a filter in her for a year, two years, three years, four years after they received a filter like the G2 Filter. True?
A. Unless they came back for a removal. 01:25PM
Q. But you didn't ask them to, right, you didn't follow them?
A. No. It's the physician's discretion on when a filter gets removed.
Q. Now, I asked you about the experience of other physicians, and we just heard from Mr. Modra. And one of the primary ways 01:25PM that Bard finds out about experiences of other physicians is when physicians voluntarily report adverse events to Bard. Correct?
A. Yes. That's one way.
Q. And we know that -- well, let me ask you. Isn't it true 01:25PM

that Bard has never formally initiated a registry to follow patients among any physician population to see how patients do after one of your devices is implanted in them?
A. I don't think so.
Q. And you know what a registry is, right? 01:26PM
A. I do.
Q. What is a registry?
A. A study, if you will, done on product that is already on the market.
Q. That's how you gather clinical data on patients who may have one of your devices in long term because you didn't have a long term study for the Eclipse device before you put it on the market, did you? 01:26PM
A. No. I disagree.
Q. What was the long term study called that related to the Eclipse? 01:26PM
A. The EVEREST trial.
Q. I'm glad you said that. So what we're talking about with respect to the Eclipse, that the information that was provided in the EVEREST trial is applicable to the Eclipse Filter. 01:27PM
True?
A. A lot of it, yes.
Q. Sir, would you agree with me that medical device companies are required to follow federal regulations with or without FDA enforcement? 01:27PM

A. I don't know what that means, but it is a regulated industry, yes.
Q. What was it you didn't understand when I asked you whether or not a medical device company was required to follow federal regulations with or without FDA enforcement? 01:27PM
A. I don't know what "with or without FDA enforcement" is.
Q. In other words, you have to follow federal regulations whether or not FDA is knocking on your door and saying follow this regulation. You have to follow your regulations, right?
A. Of course. 01:27PM
Q. Mr. Modra -- Mr. O'Connor asked Mr. Modra, FDA doesn't hang out at Bard, right?
A. No, they don't.
Q. And there's no one at Bard that hangs out at FDA, right?
A. We visit with the FDA often. 01:27PM
Q. I'm talking about was there for their everyday activities?
A. No.
Q. When you send in one of these Med Watch reports that get into the MAUDE database, you don't know what happens to it when it gets to the FDA, do you? 01:28PM
A. It gets put in the MAUDE database.
Q. That's what happens. What else besides that happens? You don't know, do you?
A. I don't know.
Q. Sir, would you agree that it's illegal to sell a misbranded 01:28PM

or adulterated medical device?
A. I would.
Q. And if a company wanted to know whether or not it was selling a device that was misbranded or adulterated, they just have to look up in the federal regulations as to what those two terms or how those two terms are defined. True? 01:28PM
A. I don't understand your question. Sorry. Yes. I can look up terms.
Q. I said if a company wanted to know whether or not it was selling a misbranded or adulterated medical device, they could look up those terms in federal regulations to see how they are defined? 01:29PM
A. Yes. We could look them up.
Q. And if as you look them up, and as they are defined, the device is misbranded or adulterated, it's misbranded or adulterated even if the FDA isn't telling you that it is. True? Is that true or not, sir? 01:29PM
A. I guess so. It's a hypothetical question. I don't know.
Q. And, sir, would you agree that the safe design of Bard filters are the exclusive responsibility of Bard and no one else? 01:29PM
A. Yes.
Q. If Bard is aware of design deficiencies in any of its IVC filters, in other words, there's data that suggests and there's discussions and analysis of your devices that say, you know 01:30PM

what, I think we ought to do something about this design. It may be increasing the risk of certain complications. You don't need the FDA to tell you it's defectively designed. It's your responsibility to know whether or not a device is defectively designed? 01:30PM

A. They are not defectively --

Q. Do you agree?

A. I do not agree they are defectively designed.

Q. I didn't ask you --

MR. NORTH: Your Honor, he's arguing with the witness. 01:30PM

THE COURT: Excuse me. Mr. Lopez, wait for the answer. Re-ask the question.

MR. LOPEZ: Your Honor, could I just ask the witness be responsive to my questions?

THE COURT: If you want to have him say yes or no, tell him that. 01:30PM

MR. LOPEZ: If okay.

THE COURT: If he asks you for a yes or no answer, Mr. Carr, you can either say yes or no, or you can say I can't answer that yes or no, in which event he can ask you another question. 01:30PM

THE WITNESS: Thank you.

BY MR. LOPEZ:

Q. Sir, if the company -- take this as a hypothetical for now. If Bard determines that it is experiencing increased, 01:31PM

unexpected complications with the design of a filter after it's been on the market for a short period of time and that they have determined that the filter needs to be designed differently, you don't wait for FDA to tell you that to know that you need to redesign the filter. True? Yes or no? 01:31PM

A. Yes, in that hypothetical.

Q. I think I have asked you this already, but would you agree that expectations and acceptability of the risks and benefits of a Bard IVC filter are exclusively the rights of a doctor and his or her patient? 01:31PM

A. I don't understand that question. I'm sorry.

Q. Well, Dr. Ciavarella understood it when I asked him at his deposition.

THE COURT: Excuse me. No more commentary on the answers. Just ask questions. 01:32PM

BY MR. LOPEZ:

Q. Sir, would you agree with Dr. Ciavarella -- who is Dr. Ciavarella?

A. He is the head of clinical affairs for Bard.

Q. Back at the time of the Eclipse Filter and the G2 Filter, 01:32PM Recovery Filter, he was the only medical doctor on the team involved with actual internal, employed by Bard team, he was the only medical doctor. True?

A. Maybe. Yes.

Q. Okay. If Dr. Ciavarella testified that expectations and 01:32PM

acceptability of the risks and benefits of a Bard IVC filter are exclusively the rights of a doctor and his or her patient, would you agree?
A. I don't understand the context. I'm sorry. I'm missing something. 01:32PM
Q. Sir, the information you, meaning Bard, provide doctors should be what is important to doctors and ultimately to patients in an informed consent situation about whether or not they choose a Bard IVC filter, a competitor's filter, or some other alternative means of treatment or therapy. True? 01:33PM
A. Yes.
Q. And there is no higher duty that a device company has than to make sure the doctor has all the risk benefit information he or she needs to decide whether or not to use the company's product, a different product, or to seek other alternatives of 01:33PM treatment for his or her patient.
Do you agree with that?
A. I don't understand what you mean by "no higher duty." Yes. We inform physicians.
Q. But I'm talking about no higher -- do you think of a higher 01:33PM duty you have as a medical device manufacturer than what I just read, and that is to make sure that doctors have all the risk benefit information they need to determine whether or not to use your product, a different product, or to seek other alternatives of treatment for his or her patient? 01:34PM

A. I think all the relevant information, yes.
Q. No higher duty. Would you agree with that?
A. Of the relevant information, yes.
Q. Let's talk a little bit about you and your life with IVC filters. You started that track when you were employed by Nitinol Medical Technologies. True? 01:34PM
A. Yes.
Q. And tell us a little bit about that.
A. Nitinol Medical Technologies was a small company in Boston that was developed by a world famous interventional radiologist named Morris Simon. And we had two primary products that we worked on. 01:34PM

One was a device to fix a hole in your heart, and then the other one was a vena cava filter. So the Simon Nitinol Filter, which is the first Nitinol device, which is what our filters are made of in the world was named after him. He was very passionate about vena cava filters. I was fortunate to come there and be one of probably about 15 employees. 01:35PM

And so we had the Simon Nitinol Filter and Dr. Simon felt that it was very important to develop a new filter that was removable. So at the time in the world there were no removable filters. So a lot of patients who could and should get filters probably weren't. 01:35PM

And so we embarked on a journey to develop that filter which the first one became Recovery, which was sold to Bard at 01:35PM

some point, 2001, and I moved to Bard in 2002.
Q. Okay. You came to Bard in 2002 because Bard had acquired NMT, right?
A. I came on my own, but yes.
Q. Well, I mean, Bard had acquired the technology of the Recovery Filter? 01:36PM
A. They had, but they chose to hire me.
Q. And there was a dispute that went on for about a year between Bard and NMT about whether or not Bard was going to buy them or someone else was going to buy that technology. Do you remember that? 01:36PM
A. Yes, before that.
Q. And during that year, basically the R&D with respect to the Recovery Filter had shut down other than the Asch study, I think, continued. True? 01:36PM
A. It didn't shut down. It was completed. The filter was essentially designed and it was being studied in the Asch Study.
Q. Nothing else was going on other than following what was going on with Dr. Asch's patients, correct? 01:37PM
A. I don't know about nothing else, but no in general.
Q. Then were you part of the due diligence team when Bard was looking at acquiring NMT?
A. I was.
Q. And isn't it true that one of the compelling reasons why 01:37PM

NMT chose Bard was because of Bard's relationship in the commercial world with doctors and they had a sales force and they had ins at hospitals?
A. The primary reason was Bard was already selling our Simon Nitinol Filter. They were already selling the Simon Nitinol Filter so they were a very logical partner to purchase the design. 01:37PM
Q. Do you recall that they had about 100 sales reps during that period of time?
A. I don't know the number. That sounds high. 01:37PM
Q. How about 10 district managers and three regional managers. Does that sound too high?
A. I don't know.
Q. Who was the marketing manager at the time?
A. At Bard? 01:38PM
Q. Yes.
A. Paul Stagg, I believe.
Q. And someone named Janet Hudnall later became the marketing manager for the Recovery Filter?
A. After it moved to Arizona. 01:38PM
Q. Now, you mentioned the Simon Nitinol filter. We have heard that a few times here. And the Simon Nitinol Filter is only a permanent filter, correct?
A. It was only a permanent filter, yes.
Q. Bard stopped selling it, what, about a year ago? 01:38PM

A. 18 months maybe. I don't know.
Q. We may talk about that a little bit later.
Now, when the Simon Nitinol Filter was being sold by NMT, and then after it was being sold by Bard -- let me rephrase that. 01:38PM
Actually, Bard was the marketing arm of the Simon Nitinol Filter even when it was being manufactured by NMT, correct?
A. Yes.
Q. And during that period of time, did Bard and NMT have to follow the same requirements of reporting adverse events to FDA? 01:39PM
A. Yes.
Q. In other words, whether or not it was a permanent filter, a retrievable filter, and whether or not the report went to Bard or whether or not it went to NMT, there was a requirement to report that to FDA, right? 01:39PM
A. I'm not sure of that, actually.
Q. But Bard was able to obtain, before they launched the Recovery Filter, whatever data that NMT had about the Simon Nitinol Filter's safety and performance. True? 01:39PM
A. Yes.
MR. LOPEZ: Okay. Could we see Exhibit 1149, please, Gay. Show it to the witness for now.
BY MR. LOPEZ: 01:40PM

Q. Sir, are you familiar with this document?
A. Only from yesterday.
Q. You saw it yesterday for the first time?
A. Yes.
Q. And, sir, if you would look at -- this is a Nitinol Medical Technologies -- do you know what a line extension to the Simon Nitinol Filter refers to? 01:40PM
A. Ultimately the Recovery Filter.
Q. And if you look at Page 17 of this document, in the first paragraph, this would have been a document that Bard would have received as part of its due diligence from Nitinol Medical Technologies. True? 01:40PM
A. I don't know where Bard got it, but I would assume so.
Q. This was about the Trademark Retrievable Filter. Isn't that another name for the Recovery Filter? 01:41PM
A. No. It's not another name. There was no name to Recovery Filter when this draft was initiated.
Q. My apologies. That is referring to what ultimately became the Recovery Filter. True?
A. Yes. 01:41PM
Q. Okay. And does this document provide information about the reports of filter fracture, the rate of filter fractures that was available to NMT as of July 1997?
A. There's a paragraph in this very early draft document that does say that. But I don't know what this document is. 01:41PM

Q. All right.

MR. LOPEZ: Your Honor, I would still like to offer this into evidence. And I could lay a foundation that it was produced to us as an NMT document bearing -- this is part of the due diligence. It bears a Bard Bates stamp number that was produced to us as a document kept in the ordinary course of business. 01:41PM

MR. NORTH: No objection, Your Honor.

THE COURT: 1149 is admitted.

MR. LOPEZ: May I publish this to the jury, Your Honor, please? 01:42PM

THE COURT: Yes.

BY MR. LOPEZ:

Q. Just to give us some perspective, the Simon Nitinol Filter was the predicate device that allowed the Recovery Filter to be cleared to be marketed in the United States. Yes or no? 01:42PM

A. Yes.

Q. And which meant that --

THE COURT: Hold on just a minute Mr. Lopez.

Check that monitor. 01:42PM

THE COURTROOM DEPUTY: Do you mind if they slide over?

THE COURT: Go ahead and slide over just two seats.

You can go ahead, Mr. Lopez.

MR. LOPEZ: Thank you, Your Honor.

BY MR. LOPEZ: 01:43PM

Q. As a predicate device, in order to be cleared, it is required that the Recovery Filter had to be substantially equivalent to the Simon Nitinol Filter from a safety and effectiveness standpoint. True.
A. As well as the Greenfield Filter. 01:43PM
Q. As well as the Greenfield. Both. Not either but both, right?
A. They were both predicate devices.
Q. And we heard from Carol Vierling earlier today who ultimately testified that even the clinical data as it relates 01:43PM to the Simon Nitinol Filter was important to consider for substantial equivalence. Do you agree with that?
A. I think all of the data is important.
Q. Here's the data that Bard had in a 1997 document about fractures associated with the Simon Nitinol Filter. 01:44PM
As of 1997, how long had the Simon Nitinol Filter been on the market?
A. Six years, I believe.
Q. Actually, it says that NMT --
A. Nine years. 01:44PM
Q. Over nine years. What does in vivo experience mean?
A. In humans.
Q. In people, right?
A. Yes.
Q. And NMT has reviewed their clinical trial database, their 01:44PM

post-marketing complaint files, and the literature to identify any fatigue-related issues associated with the SNF. That's the Simon Nitinol Filter, correct?
A. Yes.
Q. And there were two reports of asymptomatic filter fracture identified for a rate of 0.006 percent. Did I read that correctly? 01:44PM
A. You did.
Q. Then it cites McCowen 1992. Do you see that reference?
A. I do. 01:45PM
Q. And NMT has concluded that fatigue of the SNF has not been a clinical problem. Bard knew that in 1997, right?
A. If they read the document, yes.
Q. They should have read the document if they were doing their due diligence, number one; number two, if they were going to 01:45PM establish substantial equivalence for the SNF they should have known about this clinical history. Would you agree with me?
A. No, I don't agree because this is a very early draft with very little information in it.
MR. LOPEZ: Let's go to Exhibit 1613, please, Gay. 01:45PM Very first page.
BY MR. LOPEZ:
Q. Sir, who is Cindi Walcott?
A. She worked in our quality department.
Q. And you heard me talk about Dr. Ciavarella? 01:46PM

A. Yes.
Q. And Dr. David Ciavarella was the medical director at Bard, correct?
A. He said he's had various roles.
Q. This is regarding Recovery Filter detachments. Do you see that? 01:46PM
A. In the subject, yes.
Q. And earlier today Mr. Modra clarified that a detachments mean fractures. Would you agree with that?
A. I would. 01:46PM
Q. And does this provide additional information to Bard about the history of the Simon Nitinol Filter?
MR. LOPEZ: Gay, could you call out that second full paragraph where it says "today."
Your Honor, I'd like to offer this Exhibit 1613 into evidence at this time and ask for -- 01:46PM
MR. NORTH: No objection. I'm sorry. No objection.
THE COURT: Admitted.
MR. LOPEZ: May I publish it to the jury?
THE COURT: Yes. 01:47PM
BY MR. LOPEZ:
Q. This is in 2004. This is about seven years later, right?
A. Yes.
Q. And if Bard was doing their duty in fulfilling their obligation they would have been tracking the Simon Nitinol 01:47PM

Filter just like they were tracking the Recovery Filter with respect to complaints from doctors, right?
A. Yes.
Q. And making sure those got reported to the MAUDE database. True? 01:47PM
A. No.
Q. No?
A. I don't think everything was reported at that point. The instructions on what to report have changed over time.
Q. In reality, this the data here has nothing to do with 01:47PM MAUDE. This is data that Bard has. They didn't have to go to MAUDE to get the information that's contained in this document, right? This is information that Bard had internally in their own files. Agreed?
A. Yes. 01:48PM
Q. In fact, this reads: Today I reviewed all detachments reports as complaints for our Simon Nitinol vena cava filter, SNF. Our electronic database goes back to 2000. There were just two reports of fractures/detachments out off 67,800 global units sold during this time frame. 01:48PM
Did I read that correctly?
A. Yes, you did.
Q. And this only goes back to 2000, so we don't know what happened between 1997 and 2000, at least with the documents I have shown you thus far. Correct? 01:48PM

A. Yes.
Q. But we know as of 1997 the complaint -- the fracture rate was .006?
A. We know the reported fracture rate was 006.
Q. You don't know what the real rate is because you never did a study that would follow patients beyond 180 days to see how many fractures people might have if they had the device in for one year, two years, five years, 10 years. True? 01:49PM
A. Yes. We did not do that study.
Q. Thank you. Now, during the entire time that the Simon Nitinol Filter was on the market, did there ever have to undergo any design changes? 01:49PM
A. Yes.
Q. Any design changes that made it more durable to migration or fractures? 01:49PM
A. I don't know about fracture. Not migration.
Q. Did you ever have to do a health hazard evaluation with respect to any adverse events that were being reported to Bard about the Simon Nitinol Filter?
A. No. 01:49PM
Q. It was sold internationally, too, wasn't it?
A. Yes, but not very many places.
Q. Were there any internal discussions within Bard about the Simon Nitinol Filter that involved any controversies regarding its design, its safety, or performance? 01:50PM

A. Yes.
Q. And when did that happen?
A. It happened periodically because the design of the filter, many people didn't like the design because of how it was deployed. It deployed into the vessel differently than other filters. And some would say it was difficult to put in the right place all the time. 01:50PM
Q. Did anyone ever say that 2 out of 67 fractures was too many fractures and we ought to redesign this thing to take care of fractures? 01:50PM
A. No.
Q. In fact, how about migration? There were virtually no reports of migration with the Simon Nitinol Filter?
A. No. That's not true.
Q. If I were to look in your database, I mean, in your tracking and trending of the complaints that Bard received on migration, would I see anyone who -- well, let me take that back. I'm talking about adverse events from the field. Do you understand what I'm saying? Complaints that get reported to Bard, anybody who had a serious injury that caused them to be hospitalized by a migration of a Simon Nitinol Filter? 01:51PM
A. I think there have been, yes.
Q. If there had been it better be in your files. Right?
A. Unless it happened before 2000, like you said.
Q. And if it's not in your files, you are just making that up. 01:51PM

Wouldn't you agree with me?
A. No, I'm not making it up. There's literature. There's communication. There are many ways that complaints come into our system.
Q. When I look at the tracking and trending there are reports that Bard does where they list the Simon Nitinol Filter, there are virtually no migrations reported. We're talking about single digit migrations, aren't we? 01:51PM
A. I don't know. I would have to look at it.
Q. You don't know the answer to that question? 01:52PM
A. Yes. I don't know the answer to that question.
Q. We'll just let that document number speak for itself, right?
A. This document speaks for itself.
Q. I'm talking about the tracking and trending that actually lists the number of migrations and fractures for a Simon Nitinol Filter. That's the information you would need to know what that number was. True? 01:52PM
A. I don't know what you are talking about. Sorry. Yes, if there was that document, I would assume it were true. 01:52PM
Q. Now, we just heard from Dr. Asch. You know who Dr. Asch is, right?
A. I do.
Q. Have you ever read his deposition or any of his prior sworn testimony? 01:52PM

A. Maybe pieces of it.
Q. And you knew Dr. Asch back when he was performing the retrievability study for the Recovery Filter. Isn't that true?
A. Yes. I knew him well.
Q. And tell us about your involvement with that pilot study with Dr. Asch. 01:53PM
A. So it's not a pilot study.
Q. That's what he calls it.
A. It's not true. It's a special access study. And so I was the person at NMT who liaised with Dr. Asch most of the time. 01:53PM
I have spent a lot of time in Toronto at cases supporting him however he needed.
Q. So you were aware of the fractures and the migrations that happened in that study?
A. I was aware of the one fracture and the one migration that happened. 01:53PM
Q. You weren't aware that there were two fractures in that study?
A. I think they were the same filter is my recollection.
Q. Two fractures, though, in the study? 01:53PM
A. Okay.
Q. For one filter. Do you remember that?
A. Yes.
Q. And I think you even had meetings with Dr. Asch and Dr. Kaufman about the migration that happened in that study? 01:54PM

A. With others, yes.
Q. Now, when you were at NMT --
MR. LOPEZ: Can we see trial Exhibit 4554 please? Trial Exhibit 4554?
BY MR. LOPEZ: 01:54PM
Q. You are familiar with this document?
A. I haven't seen it in a long time.
Q. It's been about two months.
A. I don't recall seeing this, no.
Q. Could you go to Page 7 of this document. 01:54PM
I'm going to ask you, sir, when NMT was first designing the Recovery Filter and doing its animal study and was going to Dr. Asch to do his special access -- is that what you call it, special access study?
A. Yes. 01:55PM
Q. It was designed to have -- to look for whether or not the device could be retrieved safely within 12 weeks. Would you agree with me?
A. The animal study was.
Q. And wasn't Dr. Asch's study also designed to determine 01:55PM whether or not it could be removed within 12 weeks?
A. I would have to review the protocol. I don't know for sure.
Q. I believe this one is already in evidence, Your Honor, 4554? 01:55PM

THE COURT: No, it's not.
MR. LOPEZ: May I offer it at this time?
MR. NORTH: No objection, Your Honor.
THE COURT: Admitted.
MR. LOPEZ: May I publish it to the jury, Your Honor? 01:55PM
THE COURT: Yes.
MR. LOPEZ: Can we look at Page 1, Gay, please, so the jury can get an idea what this is?
This is from NMT Medical, Inc., and the date is May 22, 2000. 01:55PM
Do you see that, sir?
THE WITNESS: Yes, I do.
MR. LOPEZ: Can we go to Page 7, please, Gay?
And could you make the actual table there larger?
BY MR. LOPEZ: 01:56PM
Q. And this is about the Recovery Filter. Isn't Dr. Asch's study already ongoing at this time?
A. Yes, I believe so.
Q. And this was -- the Recovery Filter was -- the idea was that it would be a permanent filter that you could remove long 01:56PM term, meaning 12 weeks. That's how it was defined by NMT when they did this study, right?
A. That was the data we had. This is a presentation to Boston Scientific back during the time you were talking about when the litigation was going on. 01:56PM

Q. And the Recovery Filter is the ideal vena cava filter because it would have the same strengths as permanent filters. True?
A. That's what it says, yes.
Q. And it would also involve accurate placement, enhanced centering, small sheath. Do you see where it says that? 01:56PM
A. Yes.
Q. And it would be removable at 12 weeks. True?
A. Yes.
Q. And, in fact, Dr. Asch's study didn't establish safety of retrievability beyond 12 weeks, did it? 01:57PM
A. I think there were many removals far past 12 weeks.
Q. There were, but the design, the mean period of time, meaning the average period of time for retrievability was less than 12 weeks. True? 01:57PM
A. I don't know. I would have to see that.
Q. Did it follow patients for more than a year who had the device in them to see if the devices could be safely removed after one year?
A. Yes. Oh. I think the longest might have been 183 days. 01:57PM
Q. That was how many patients?
A. That's the longest.
Q. One patient?
A. That one was, yes.
Q. So the best data that Bard had clinically that a Recovery 01:58PM

Filter could be safely removed if left in after 12 weeks was one patient where it was left in for 183 days. True?
A. No. I said that was the longest.
Q. But did you follow any of these patients after 183 days of implantation? 01:58PM
A. I don't think so, no.
Q. So you don't know anything about what happened to those other patients who did not have their devices removed after 183 days?
A. They weren't part of the study, no. I don't know. 01:58PM
Q. Well, they weren't part of the study because once the study was over they were told if they kept it in they were left to whatever happened to them, right?
A. Yes, like all clinical studies.
MR. LOPEZ: Can we go to Page 9, please, of this exhibit. Again, this talks about -- that's Page 9. Let's go to 21 instead, Gay, please. 01:58PM
BY MR. LOPEZ:
Q. I think this is the animal study that you mentioned earlier, I think, that we talked about earlier, isn't this in the Recovery Filter In Situ six-week residence? 01:59PM
A. No.
Q. This isn't the animal study? What is this?
A. This is a animal study.
Q. It's a animal study. Okay. But this is an animal study to 01:59PM

see if it could be removed within six weeks?
A. No. This is a study to look at the filter implanted at six weeks.
Q. And then it was removed after six weeks?
A. No. They were not all removed. 02:00PM
Q. Some of the animals were sacrificed without the device being removed?
A. I don't know in this study. This isn't our study that we used to support our submission.
Q. What does a six-week residence study mean? 02:00PM
A. It means the filter was implanted for six weeks.
Q. And let's go to the next slide, Page 22. 12 filters removed from 12 animals. This is a 12-week removal study. That's what this is talking about, right?
A. Yes, it is. 02:00PM
Q. And 100 percent of those were successful?
A. Yes.
Q. And was there ever an animal study done where any of those devices were left in beyond 12 weeks?
A. No. 02:01PM
Q. Next slide, please. One more.
Now, the human experience would be the Asch study, correct?
A. Yes.
Q. Let's look at the presentation here. So this is Dr. Asch. 02:01PM

There had been one removal to date in 10 days. Do you see that?
A. I do.
Q. Next slide, please.
And then this talks about the plan for there to be a European -- I'm sorry -- that this would be submitted for a European -- for a 12-week removal. Do you see that? 02:01PM
A. I see it says that. Doesn't say it will be done, was just a potential.
Q. So the regulatory submission in Europe was going to be for a 12-week removal. That's what it says, correct? 02:02PM
A. Potentially.
Q. And OUS, what does that mean? Outside the United States?
A. It does.
Q. That was also going to be a regulatory submission for 12-week removal, correct? 02:02PM
A. It says following 12-week removal. I don't know what the indication was.
MR. LOPEZ: Next slide, please. Go back one. 27. Blow that up, please. 02:02PM
BY MR. LOPEZ:
Q. This is the U.S. plan for commercialization in 2000. Would you agree that's what that says?
A. This is a potential plan as we are telling a potential buyer to what could be done with the device. 02:03PM

Q. Right. And in every slide that we have seen thus far, the plan was for the Recovery Filter to be safe and effective for a 12-week retrievability and thereafter converted to a permanent device. True?
A. No, I don't believe that. 02:03PM
Q. You don't believe that's a fair reading of these slides?
A. No. The only data we had was a 12-week animal data so that's what we were representing here.
Q. And the human data you had was an average implantation of 53, 54 days. 02:03PM
A. No. It was actually only four patients at the time with one explant of 10 days. So this was very early in the Asch study as well.
Q. I'm talking about later after this, after the animal study. Dr. Asch just testified here a couple days ago that the mean 02:03PM retrieval was 53, 54 days. I don't remember exactly. That was the average period of time that he retrieved devices safely in his study.
A. I'm sorry. Is that a question?
Q. Well, do you agree with that? 02:04PM
A. I have no idea.
Q. Do you disagree?
A. I don't know what he said.
Q. Sir, you came here today. You knew I was going to ask you about the Asch study, right? I asked you about it two months 02:04PM

ago.
A. You asked me a lot of questions over time.
Q. You know how important the Asch study is to this case, don't you?
A. To this case? 02:04PM
Q. Yeah.
A. No.
Q. Well, you have been asked about the Asch study a lot at depositions and two months ago when you were testifying under oath? 02:04PM
A. That was for a different filter.
Q. Okay. But you know how important the Asch study is. Dr. Asch testifies here you knew he was testifying, right?
A. No. I found out he was testifying.
Q. And you didn't think it was important for you to come 02:04PM prepared to discuss the details of the Asch study when I was asking you questions about that, about important information that the jury might want to know and maybe should know. True?
MR. NORTH: Objection. Argumentative.
THE COURT: Sustained. 02:05PM
BY MR. LOPEZ:
Q. Now, let me ask you some questions about the Patient 9 and Patient 33 real quickly.
There was no root cause analysis ever done on either one of those two patients. True? 02:05PM

A. No, I don't think that's true.
Q. Well, root cause analysis would include what the fix would be, what the solution would be. Wouldn't it?
A. No. Sometimes you can't find a solution.
Q. Well, the root cause -- and it's not a root cause analysis if you don't come up with a solution. That's a definition of a root cause analysis. True? 02:05PM
A. Absolutely not. A root cause analysis is to try and figure out what happened. It doesn't mean -- excuse me -- it doesn't mean you will. 02:06PM
Q. Why did the Recovery Filter migrate four centimeters after being challenged by a clot in the Asch study?
A. I don't know.
Q. Why did it fracture?
A. Our hypothesis is that it fractured because of the woman who the filter was in was pregnant and gave birth to a child. And we believe that the forces that were put on the filter at that time probably caused it to fracture. 02:06PM
Q. But you didn't do any bench testing or other testing where you replicated those forces to see if maybe that was the cause of the fracture? 02:06PM
A. I don't remember either way.
Q. And once you had a fracture after that Recovery Filter was on the market, and it was not a pregnant woman, you should have concluded at that time it wasn't because of a pregnancy. True? 02:06PM

A. If the woman wasn't pregnant we would not conclude that it was because of a pregnancy. True.
Q. And if it happened in a man it certainly wasn't related to a pregnancy. True?
A. Chances are good, yeah. 02:07PM
Q. And then after the Recovery was on the market, it started experiencing similar migrations to the migrations that were experienced in Dr. Asch's study. True?
A. We had migrations.
Q. Did you ever figure out why any of those devices were migrating? 02:07PM
A. Yes.
Q. And why were they migrating?
A. Different ones for different reasons. But normally because they were overwhelmed by a massive clot. 02:07PM
Q. They were relating to the way that the device was designed. Would you agree with me?
A. Yes.
Q. And prior to the Recovery Filter being on the market, other than the Asch study, most of the data that Bard had was done on 02:07PM what we call bench testing. True?
A. We had bench testing. We had animal testing. Then we had the Asch study. That's the sequence of events.
Q. Would you agree that the goal of bench testing is to replicate a real world. It was what might actually happen in a 02:08PM

real person?
A. To the best of your ability for some tests. You can't do that for everything.
Q. But you need to take into consideration foreseeable circumstances, the environment of use, all of those things. 02:08PM
Those should be well studied if you are just going to see whether or not a device is safe in basically a test tube?
A. Yes, to the best of your ability at the time.
Q. And Mr. North yet in his opening statement described that environment, I think, quite accurately and graphically. The 02:08PM
IVC filter is a challenging environment. Would you agree?
A. The vena cava is a challenging environment.
Q. I'm sorry. The vena cava is a challenging environment.
A. We've come to learn that, yes.
Q. And he also said that it's a harsh and dynamic environment. 02:09PM
Do you agree with that?
A. Yes.
Q. This is not a stationary tree trunk. Do you agree with that?
A. Sure. 02:09PM
Q. All sorts of stresses happen in the vena cava when you are trying to design one of these filters. Do you agree with that?
A. Yes.
Q. You have flattening?
A. You can. 02:09PM

Q. You have cross-sectional expansion?
A. Yes, you can.
Q. And you have longitudinal stress. True?
A. Yes.
Q. And those are things that were well known about the vena cava filter 15, 16 years ago. True? 02:09PM
A. Absolutely not.
Q. When you say "absolutely not" you mean there was no textbook, there was no doctor, there was nothing that you could reference that would show how the vena cava acts in a human body? 02:10PM
A. Not to my knowledge, no.
Q. Did you do any research yourself?
A. We did plenty of research altogether.
Q. And you learned later -- so you learned after you tested and put the device on the market about this dynamic and challenging and harsh environment in which a vena cava was being implanted? 02:10PM
A. We learned new things for sure, and we always do based on new imaging, based on experience. 02:10PM
Q. And would you also agree that a PVC pipe with sausage casing as the test environment for an IVC filter is not the type of environment that Mr. North described in his opening statement?
A. I don't understand. Sorry. 02:10PM

Q. Well, in other words, a rigid PVC pipe with a sausage casing is not a challenging, harsh, environment, dynamic environment like Mr. North described in his opening statement. True?
A. If you are speaking of the migration study, it's not a rigid PVC tube. It does have sausage casing in it which does, in fact, mimic the vena cava as best we can. And it is a pretty harsh environment, because you are trying to make the device move. 02:11PM
Q. And that's how it should be tested in its Environment of Use? 02:11PM
A. That's how it is tested for the last 20 years.
Q. No, I mean it should be tested -- well, that's not how it was tested after it was put on the market and put in a real human being. You didn't test it in a test tube in a sausage casing that mimicked the human condition, did you? 02:11PM
A. We tested exactly what I just described long before the filter was ever on the market, yes.
Q. And it's your testimony that PVC pipe and sausage casing is mimicking the real condition of a human being's vena cava? 02:12PM
A. No, I'm not saying that because it didn't use PVC pipe, first of all.
Q. What kind of pipe was it?
A. It's a silicone tube with sausage casing put in, and yes, the sausage casing does mimic the vena cava because it gives 02:12PM

the hooks of the filter a place to engage that is a natural material. It's not a vena cava filter. But it is the best we can do to make a test that you can do time and time again to compare to.

Q. Okay. Now, when you ran those tests with the Recovery Filter, the bench test you just described, there was no -- there didn't seem you had any issues with migration when challenged by a clot. True? 02:12PM

A. I don't know what you mean by "issues."

Q. You didn't have the test, run the test, and after you ran the test you say, well, the way this is designed when it gets challenged by a clot it's going to push the filter off its current location? 02:12PM

A. Of course we did. That's the goal of the test.

Q. So you thought you had migration issues with the Recovery Filter when you were testing it on the bench? 02:13PM

A. No. The goal of the test is to determine the force or pressure at which every filter migrates. We want it to migrate in that test.

Q. Okay. I understand. But after running those tests, you determined that from a migration resistance standpoint the Recovery Filter was safe to implant in a human being? 02:13PM

A. Yes.

Q. Yes or no?

A. Because they met the internal acceptance criteria. 02:13PM

Q. So you determined after running the test that based on the results of that test, we can implant these in human beings. True?
A. No. We did a lot of other tests first.
Q. Then once you -- but all those other tests that you did resulted in you determining that this device can at least be implanted in patients in Dr. Asch's study. True? 02:13PM
A. After all of the testing we did on the bench and in the animals, yes.
Q. Okay. 02:14PM
A. We applied for a special access study and were granted that.
Q. All right. Now, the first time that the device gets challenged by a clot in Dr. Asch's study, it starts to migrate towards the heart. You are aware of that happening, right? 02:14PM
A. It did migrate, yes.
Q. In fact, I think you agreed when we asked you this question that if this patient wasn't in a clinical study and being closely monitored there was some concern that that clot could have continued up and went into the patient's heart? 02:14PM
A. The concern was if we didn't know what could happen to the filter.
Q. Right. And it was a good thing that he was being closely monitored in a clinical trial. Right?
A. Yes. That's how we observed it. 02:14PM

Q. Now, sir, this simple question, didn't that human experience give you folks at Bard evidence that however you were testing it in a laboratory was not giving you the kind of results that would happen in a real human being?
A. No. 02:15PM
Q. Okay. So you were anticipating this migration that happened in Patient Number 9, the first and only patient that was challenged by a clot in the Asch study? Yes or no, sir. Would you anticipating that happening?
A. I can't answer that question yes or no. 02:15PM
Q. And Mr. North said in his opening statement that Bard's process is to learn from their clinical experience. We assessed our experience with Recovery and created the G2.

That experience, that clinical experience with the Recovery happened after it was launched on to the open American 02:16PM marketplace. True?
A. Partially.
Q. When you say "partially," I don't understand what you mean. Was there another clinical trial going on that we don't know about after it was launched? 02:16PM
A. No. We had the Asch study that we talked about and we had the commercial experience.
Q. I'm talking about after it was launched, the only clinical experience that Bard was using to assess the performance of the Recovery Filter was what was happening in the open marketplace. 02:16PM

True?
A. Yes.
Q. And doctors weren't being told to follow these patients so that they could report back to Bard how they were performing. It would be up to a doctor to voluntarily report those events if he or she decided it was something they should report. True? 02:16PM
A. Which is true for everything.
Q. Well, sir, is that true or not, that Bard was not following these patients. They were relying on doctors, other doctors to follow the patients and maybe report those back to Bard. True? 02:17PM
A. Yes. That's true. Doctors monitor their patients, we don't. And if they choose to report to us, they will.
Q. Right. But Bard didn't put out, when they put the Recovery Filter out in the market, tell doctors I want you to monitor these patients and let me know if you see a fracture like we saw in the Asch study. Let me see if you see a perforation or a tilt like we saw in the Asch study, or let me know if you see fractures like we saw in the Asch study. Bard never gave those instructions or that information or advice to doctors. True, sir? Yes or no? Can you answer that yes or no? 02:17PM
A. No, I can't.
Q. Before Bard launched the G2, did it have -- did it do any clinical study at all on the G2?
A. Not before we launched as a permanent, no. 02:18PM

Q. So before it went into the open marketplace, you didn't even do an access, special access study like what you did with the Recovery Filter. Right?
A. No, we did not.
Q. You did some bench testing. You made some design changes to it. You changed the name from the Recovery to the G2, and you launched it? 02:18PM
A. No. That's not what we did.
Q. You didn't do any clinical trial work, did you?
A. No, we did not. 02:18PM
Q. You had no idea how it was going to react and respond in patients before it was launched. True?
A. No.
Q. That's not true?
A. Correct. 02:19PM
Q. You actually had -- you actually knew how it was going to react and respond in patients before it was launched?
A. We had testing that showed it was significantly better than its predicate device.
Q. You had bench testing. 02:19PM
A. And we had animal testing.
Q. You had animal testing. What kind of animal testing?
A. The exact same tests we did in Recovery.
Q. Which was?
A. 12-week implant and removal for safety. The idea of the -- 02:19PM

Q. I'm sorry. I just want to make sure we're on the right page. Before the permanent device was launched?
A. Yes. We did animal work to show that when you remove the device that it doesn't significantly damage or in any way harm the vena cava. That's the risk of removal. 02:19PM
Q. Okay. My question was that's to determine whether it's retrievable. Was there any clinical, human clinical data on its safety and effectiveness as a permanent device?
A. No.
Q. Before it was launched? 02:20PM
Okay. So it was launched without any clinical data about long term safety and effectiveness as a permanent device. True?
A. Yes, but it relies on its predicate also.
Q. And then without having any clinical data on the G2 Filter before it was launched, did you advise physicians who might be prescribing the G2 Filter that they ought to monitor those patients closely since -- and see whether or not the G2 is actually going to perform safer than our Recovery Filter? Did you give that advice to doctors? Yes or no? 02:20PM
A. No.
Q. Before -- by the way, we talked a little bit about the sales force and the marketing department. And Mr. O'Connor talked to Mr. Modra about it a little bit today. The face of the company, the people that interact most with doctors and 02:21PM

hospitals are the sales force, right?
A. Sure.
Q. They are in doctor's offices every day?
A. Hopefully.
Q. And their purpose is to sell Bard products, including IVC filters. Right? 02:21PM
A. The ones who sell filters, yes.
Q. And if doctors have questions -- by the way, do you know what fair balance means when it comes to marketing and selling medical devices? 02:21PM
A. Yes.
Q. What does that mean? Explain that to the jury please.
A. That your promotional equipment or your promotional documents are fair and balanced to competition.
Q. And they must be fair and balanced, meaning you can't just tell them how wonderful the device is. If you have information about risks that doctors don't know about, you have to tell them about those risks so that they can do a risk benefit analysis themselves. True? 02:22PM
A. Not in a marketing brochure, no, I don't think so. 02:22PM
Q. No, but I thought when you are marketing, when your salespeople are having conversations with doctors?
A. Those are in the IFU.
Q. When they are having conversations with doctors, salespeople should be armed with data about Bard filters in 02:22PM

case the subject comes up about the safety and effectiveness of Bard filters. True?
A. Generally, yes.
Q. And if there is information that might influence a doctor to not use a Bard filter over safety concerns, and only Bard has that information, Bard ought to arm their salespeople with that information to share with doctors. Yes or no? 02:22PM
A. Can't answer that yes or no. It's a hypothetical question.
Q. Mr. North's comments about clinical experience, how the company learns how a product's performing because they are getting information about their clinical experience as it's being sold, that clinical experience that Bard's learning about is probably clinical experience that doctors ought to know about, too. Don't you agree? 02:23PM
A. In general. 02:23PM
Q. And you have information. We went over some complaint files earlier today. Bard doesn't only get reported, we had a fracture, they are supposed to investigate fractures. They are supposed to contact the health care provider and learn as much as they can about these complications. True? 02:24PM
A. About every complaint, not just fracture.
Q. Right. And the reason they do that is because they might learn something about their performance of their device that may cause them to maybe reconsider the design of the product. True? 02:24PM

A. Of course. We use that data all the time to improve devices constantly, no matter what the device is. That is the primary form of feedback when the device is commercial.
Q. And, sir, wouldn't you agree that if it was important information for Bard to learn about for purposes of whether or not they might want to redesign their product for a safety reason that that same information would be important to pass on to doctors and patients. Yes or no? 02:24PM
A. If it were for safety, yes. But we're not talking about safety for every complaint. 02:25PM
Q. But certainly if it dealt with a safety concern, an injury that doctors may not appreciate about your device, that's certainly something that you ought to pass on to doctors so that they know about it. Right?
A. No. I don't agree with that in general. 02:25PM
Q. Well, sir, aren't you -- you know that doctors sometimes will have a bad experience with a device, and if they share that experience with one of their colleagues they may cause both of those doctors to not use that device again. You are aware of that, right? 02:25PM
A. Yes.
Q. As a matter of fact, you were aware of that in 2005 when you and Janet Hudnall decided it would be a good idea for her to go out and interview some of Bard's most significant customers, physicians who were having issues with the Recovery 02:26PM

Filter. True?
A. No. It wasn't me and Janet Hudnall.
Q. Let's look at Trial Exhibit 0753. While she's calling that up, Mr. Carr, I apologize. I know it's on the screen, but let me ask you a question. 02:26PM
You said not every report, but certainly, if there were reports or a trending of reports that involved tilt, migration, perforation, fractures, embolization of pieces of the device to the heart or lung, that would be the kind of information that would be relevant information for other 02:26PM
doctors to know about. True?
A. Only if it reached a certain level, if there was a safety risk.
Q. I'm talking about information that might influence a doctor to not use your device because of an experience of another 02:27PM
doctor. You are familiar with that concept, aren't you, as a former marketer?
A. I have never been a marketer.
Q. You are familiar with that concept?
A. That if somebody talks to somebody also and they choose not 02:27PM
to use it? Yes.
Q. Right. And if you look at Trial Exhibit 753, and I can show you the deposition. But you were the 30(b)(6) witness for this particular event?
A. I don't have that exhibit. 02:27PM

MR. LOPEZ: Will you stipulate to that, counsel?

THE COURT: Mr. Lopez, let's ask questions of the witness not of counsel.

MR. LOPEZ: I'm going to have to look at the deposition then, Your Honor. This is the October 29, 2014 deposition, Trial Exhibit 753. Actually, let's not do that. Let's just look at the document. I think I can lay a foundation with this witness. 02:27PM

Gay, I'm sorry, could you put back up Trial Exhibit 753? Oh. 755. Apologize. 02:28PM

BY MR. LOPEZ:

Q. Do you have 755 in front of you?

A. Yes.

Q. You are familiar with this e-mail and these events?

A. Yes. 02:28PM

Q. ?

A. I don't know if I have seen this e-mail. I guess I have in a previous deposition.

Q. We can go to the next page. Might help you.

A. Yes. 02:29PM

Q. Okay. And did you have a meeting with Janet Hudnall about the events that are described in this e-mail?

A. I don't recall one. I'm not on this e-mail anywhere.

THE COURT: We're going to break at this point, Mr. Lopez. 02:29PM

Ladies and Gentlemen, we will resume at 2:45. I will excuse you.

(Recess from 2:29 p.m. until 2:47 p.m.

You may continue, Mr. Lopez.

BY MR. LOPEZ: 02:47PM

Q. We were talking about Exhibit 755, Mr. Carr. I think it should be still on your screen. Anyway, you are familiar with this event that's described in this document, this road show, the G2 road show, correct?

A. I'm familiar with the document, yes. 02:47PM

MR. LOPEZ: Go to, Gay, Number 3 of the document 755-03.

Your Honor, may I offer this into evidence at this time and ask that it be published to the jury?

MR. NORTH: No objection, Your Honor. 02:48PM

THE COURT: Admitted, and you may publish.

MR. LOPEZ: Thank you.

And Gay, would you please enlarge the first full paragraph of Page 3 of this exhibit.

BY MR. LOPEZ: 02:48PM

Q. And this is from -- you can see this is from Janet Hudnall. Do you see that?

A. Yes.

Q. And Janet writes -- and just to give the jury the proper perspective and date, this is in July of 2005. Can you confirm 02:48PM

that, sir, from the e-mail?
A. No, I can't.
MR. LOPEZ: Go back to Page 1, Gay, please. March of '05. Go to Page 2.
BY MR. LOPEZ: 02:49PM
Q. Okay. This is in March of 2005. Do you see that?
A. Yes.
Q. And that's about the time when Bard was already redesigning the Recovery to become the G2, to replace the G2 on the marketplace because of some safety issues regarding the 02:49PM
Recovery Filter. True?
A. I think it's just before the release of it.
Q. And actually, the intent was to release it then but it didn't release until a few months later. Right?
A. I don't know for sure. 02:49PM
Q. And Janet writes: As we gear up for the release of the modified Recovery. So the jury understands what that means, modified Recovery is the G2, correct?
A. Yes, it is.
Q. One of the things I'm going to do is personally visit those 02:49PM
accounts that need a little extra attention and formally introduce the modifications.
Do you see that?
A. Yes.
Q. And what she means by that, these are people who have been 02:50PM

using or known to have been customers of Bard who were using the Recovery device?
A. I assume so.
Q. And these could be accounts that have been skeptical but have large potential upside or high profile accounts that could affect other accounts in the area. 02:50PM
Do you see that?
A. Yes.
Q. In other words, there was a concern that some of the doctors who may have been having some bad experiences with the Recovery Filters might share with their experience with other doctors that could affect other doctors using the Recovery Filter. Do you agree with that? 02:50PM
A. I agree that could be a concern. I also think that she's being proactive and introducing the new device to potential clients. 02:50PM
Q. Okay. We'll see.
MR. LOPEZ: Let's go to the next page, Gay, please.
BY MR. LOPEZ:
Q. Okay. So now, this is September of 2005. And if you look at the first full paragraph, this is still talking about the G2 Filter road show. Do you know why it was called a road show? 02:51PM
A. She was going different places on the road. I don't know.
Q. And she was getting a list of the accounts from her various district managers as to whom they believed should be the 02:51PM

customers for her to go visit. Correct?
A. It says a list of road show accounts, yes.
Q. And let's go to the next page, please. Keep going.
And is this a list of the various accounts and hospitals that Janet was asking for to have -- to be able to determine who to go visit about the Recovery and G2 Filter? 02:52PM
A. I don't know. I assume so.
THE COURT: Folks, somebody has their phone on. If you could all please turn your phone off, not just on mute. That buzzing we're hearing is a phone interfering with the system. 02:52PM
MR. LOPEZ: Excuse me one second. Let's try Trial Exhibit -- is this part of 755 now? Okay.
I apologize, Your Honor.
BY MR. LOPEZ: 02:54PM
Q. Exhibit 755, Page 14, do you recognize this document, sir?
A. I have been shown it before, yes.
Q. And this is the priority accounts that were discussed in the earlier e-mails. True?
A. Probably. I'd have to check. 02:55PM
Q. Okay. And these -- this is the information that Janet Hudnall was gathering as she was doing her G2 road show?
A. I assume so.
Q. And these are -- when western region G1A Recovery, that's referring to the G2. In other words, if you see G1A in some of 02:55PM

these documents, it actually refers to the G2?
A. Yes.
Q. And these are priority. Priority accounts would be what?
A. You would have to ask her.
Q. And these are like say, for example, this first doctor, 02:55PM
he's from Austin, Texas. And the annual value, I mean, the annual volume is listed so before she went out she knew how much value that these particular doctors had to Bard, correct?
A. Of course. We know all of our data.
Q. And this doctor just heard of a migration, just heard about 02:56PM
it, and that was enough for him to not use the Recovery Filter?
MR. NORTH: Objection, Your Honor. 602.
THE COURT: Overruled. The witness can answer if he knows.
THE WITNESS: I have no idea. 02:56PM
BY MR. LOPEZ:
Q. Isn't that how you would interpret that under comments, that Dr. Reifsnyder heard of migration and won't use?
A. That's what the document says.
Q. And another doctor from DeMoines, Iowa, he got a letter and 02:56PM
just from getting a letter he had a fear about the migration problems with the Recovery Filter. See that?
A. I do.
Q. And then there's a doctor who is from California whose name is redacted, and he stopped using it due to several reported 02:56PM

complications, just reported complications. And that doctor stopped using it, right?
A. I don't know if he stopped. That's what it says.
Q. This document, the purpose of this document, the reason I'm using it, this gives Bard insight and puts Bard into the minds of what's important to doctors about their devices and what information they need about their devices to know whether or not they want to continue to use the device. Whether or not it's the right judgment by the doctor or not, this is the information that doctors want. True? 02:57PM
A. No.
Q. Let's go to the next page, please. Here's a doctor from Missouri, an $80,000 account. He stopped using it because of a migration, correct?
A. I don't know. That's what the document says. 02:57PM
Q. And another doctor from, also from Springfield, well from Missouri, $156,000 account, stopped using. He was just concerned about reported incidents. Do you see that?
A. I do.
Q. And next one, San Diego, California, 100,000, standard of care no longer Recovery concerned about patient safety. 02:58PM
Did I read that correctly?
A. You did.
Q. Let's go to the next page. Here's a doctor in Tennessee, $200,000 account, had filter fracture and seen several arms 02:58PM

outside the caval wall. Do you see that?
A. Yes.
Q. All right. And then there's a doctor from Tennessee, heard of a migration as leery, meaning he's concerned about whether or not he's going to use the device. Is that how you interpret that? 02:58PM
A. Yes, concerned. However you want to put it.
Q. If we go through this document --
MR. LOPEZ: Let's go to Page 6 of 10 of the chart, Gay, please. One more. 02:59PM
BY MR. LOPEZ:
Q. And if you look at -- let's go down near the bottom. There are doctors now in Tampa, Florida, who had fracture concerns about the Recovery Filter. Do you see that, sir?
A. I do. 02:59PM
Q. And then there's a doctor who stopped using migration from Missouri. Let's go one more page.
Anyway, this is -- you can glean from looking at this that doctors aren't waiting for certain levels of percentages or statistics, or whether or not it's consistent with an old 03:00PM device where something was reported in the medical literature. They are interested in what's going on with a device currently. And every doctor, for different purposes and different reasons, could choose to stop using, particularly a new medical device, just based on information he's hearing from other doctors. 03:00PM

Wouldn't you agree with that?
A. Of course. Anybody can do anything.
Q. But one of the advantages Bard has over doctors that are just in an office in Missouri or in Tennessee, those doctors only have access to their own local experiences. Bard's 03:01PM
getting information about the experience of doctors literally from all over the world. Isn't that true?
A. Yes.
Q. I mean, so a doctor -- the doctor in Tennessee who heard about one migration and doesn't want to use it in anymore, he 03:01PM
has no idea that there may have been 10 other doctors in other parts of the country who, before he had that one migration, each had a migration because they only reported it to Bard and Bard never reported that to that doctor. True?
A. No. 03:01PM
Q. So Bard does report the experiences of other doctors as it accumulates all of this complaint data?
A. No, we don't. We would only act if it became unexpected.
Q. Well, sir, I understand what your protocol is. But for patient safety purposes, what's important is what is the 03:02PM
protocol of physicians and doctors? What do they think is important? What's relevant to them? What risk are they willing to accept? Wouldn't you agree with me, sir?
A. That's not a question. I'm sorry.
Q. Would you agree with me that that's what's important? 03:02PM

A. No. You would have to ask the physicians.
Q. Well, you have got a number of physicians, at least you see from this road show that are telling Bard that just because they heard about a migration or they have had one migration and they are not using the device anymore, you know that there are doctors like that around the country. Right? 03:02PM
A. Yeah. They are listed here.
Q. But again, Bard has the advantage of having gathered the information from every doctor or hospital that's reported these adverse events to Bard. You have it all, right? 03:03PM
A. We have what we were given, yes.
Q. And it's not Bard's policy to share that data with other physicians to whom they are selling their medical devices, right, including an IVC filter?
A. We don't share each and every report, no. 03:03PM
Q. In fact, you don't share any of your test results with any customer that might support your claims. Right?
A. We supply our adjudicated clinical trial data.
Q. So if a doctor, we talked about this before, in the G2 brochure when you make claims about your device being -- taking 03:03PM strength and stability to a new level, where it says data on file, if a doctor calls up and asks for that data Bard doesn't give that to the doctor?
A. Correct, because that data is kind of the secret sauce to the device, those specifications, those dimensions, those 03:04PM

performance criteria are what makes our device our device. And it is a highly patented area, and there is stiff competition. So no we would not provide that generally to a physician.

Q. How about when you have focus groups with some of your consultants and they give you advice about what they think the fracture rate and the migration rate and the death rate should be about filters. Do you share that information with doctors to whom you are selling sometimes $200,000 worth of IVC filters? 03:04PM

A. I don't know what Janet shared with them. 03:04PM

Q. You have had focus group with doctors before in the middle of the G2 being on the market and having issues with the G2 migrating and fracturing, right?

A. So we didn't have issues with the G2 migrating and fracturing, but yes, we did convene two separate panels to investigate bariatric patients, which are people who have gastric bypass surgery, and then also to discuss caudal migration. 03:05PM

MR. LOPEZ: Could we see Exhibit 1452 and 1033 at the same time. For some reason they are two separate exhibit numbers but they are actually the same document. One is Page 1 and one is Page 2. 03:05PM

BY MR. LOPEZ:

Q. Sir, we talked about this document, 1452, two months ago. Do you recall that? 03:05PM

A. We talked about a different version of this document.
Q. Okay. It was a version -- you said that was -- what do you mean a different version of this document? I'm confused.
A. The document you showed me last time had notes all over it.
Q. This is the same exhibit. 03:05PM
A. I don't believe that's correct.
Q. Let's look at 1033. Maybe I'm confused. Are you saying this isn't the document you saw two months ago?
A. Yes. I am saying that.
Q. How about the document that's in front of you now? 03:06PM
A. I don't remember you showing me this page.
Q. Do you recall this document refreshing your recollection that one of your consultants thought that the Recovery --
MR. NORTH: Objection. He's reading from the content of the document. It's not admitted. 03:06PM
THE COURT: You can't read from a document that's not in evidence.
MR. LOPEZ: I'm not. I'm reading from my notes.
THE COURT: Looked like you were reading from the document. 03:06PM
BY MR. LOPEZ:
Q. Did any of your key opinion leaders ever refer to a Recovery Filter as a wimpy filter?
A. Yes.
Q. Was that Dr. Venbrux? 03:07PM

A. I don't know. The statements on the first page, I believe it was Dr. Kaufman.
Q. Okay. And this was an expert panel that you had put together to talk about issues that you were having with the Recovery Filter at that time, right? 03:07PM
A. I have no idea where this document came from.
Q. You testified about this document in March of 2018. That was two months ago. You didn't remember doing that two months ago?
A. Yes. And I told you then I don't know where the document came from. 03:07PM

MR. LOPEZ: Could we look at the Kevin Phillips, Page 187. Show it to Mr. Carr, please.

How do I switch this, Traci?

BY MR. LOPEZ: 03:08PM
Q. Sir, this is the testimony you gave in February of 2015. It was about the meeting that's represented on Trial Exhibits 1452 and 1033.

MR. NORTH: Your Honor, I'm going to object to counsel's statement. There's been no testimony linking that document to any meeting, and it's not admitted. 03:09PM

THE COURT: Mr. Lopez, your response.

MR. LOPEZ: I will have to give him another -- hold on a second.

BY MR. LOPEZ: 03:09PM

Q. Let me ask you, we're not showing this to the jury. Does this refresh your recollection that you acknowledge this document and acknowledge being at this meeting?

THE COURT: You have to have an exhibit number for whatever you are showing. 03:09PM

MR. LOPEZ: I can only refer to it as Phillips. Is there an exhibit number?

MS. SMITH: It's a trial transcript.

THE COURT: You have to give it an exhibit number if it's going to be referred to in this trial. 03:09PM

MR. LOPEZ: Could we give this an exhibit number?

THE COURT: What is it you are asking to have admitted?

MR. LOPEZ: Transcript.

THE COURT: One Page? 10 pages? 100 pages? 03:10PM

MR. LOPEZ: Three pages.

THE COURT: What's the date of the transcript?

MR. LOPEZ: Let me get a cover page. February 4 and 5, 2015.

THE COURT: All right. Do you want to bring that to Traci and she can mark it as an exhibit? 03:10PM

MR. LOPEZ: Your Honor, just in the interest of time, I'm going to pass on this. We'll do this at some other time. We don't need to do this right now.

THE COURT: That's fine. 03:10PM

BY MR. LOPEZ:
Q. Let's move on. In any event, you don't remember being at a meeting with Dr. Venbrux, Dr. Kaufman, and others about the Recovery Filter?
A. I have had many meetings with Dr. Kaufman and Dr. Venbrux. I don't remember that meeting, no. 03:11PM
Q. Now, when Janet Hudnall went out in 2005 right before the Recovery Filter, Bard was going to stop marketing the Recovery Filter and start marketing the G2 Filter. When she called on these doctors the Asch study had already been done, right? 03:11PM
A. Yes.
Q. You had already had three or four health hazard evaluations regarding some problems with migration and fractures of the Recovery Filter. True?
A. I don't know. 03:11PM
Q. You don't remember that?
A. I don't know how many, no.
Q. But you had some health hazard evaluations that related to fractures and migrations of the Recovery Filter?
A. We have over time. I don't know those dates. 03:11PM
Q. Why don't I show you one. Can I have the June 2004 HHE, please, 1219. Trial Exhibit 1219.
While we're doing this, Mr. Carr, what's a health hazard evaluation? And why does a company have to do one of those? 03:12PM

A. I don't know the definition of it. It is a the health hazard evaluation so when there's something that wants to be evaluated from a health and safety point of view, they put together these documents.
Q. And you have seen health hazard evaluations as they relate to the Recovery Filter? 03:13PM
A. I have seen some.
Q. And you have seen the one that's on the screen?
A. I don't know.
Q. But a health hazard evaluation is a report of a document that's kept in the ordinary course of business at Bard and distributed among other members of Bard as they are evaluating the risk and hazards of one of their IVC filters. True? 03:13PM
A. It is not widely distributed, no.
Q. Meaning it goes to people who should know about these events in the event that they are in a position to maybe do something to improve the product, or to potentially save people's lives. Right? 03:13PM
A. No. It does not go to everyone, no.
Q. I didn't say everyone. It goes to important people who are decision makers at Bard? 03:14PM
A. No. For example, I didn't see a lot of them.
Q. But does it go to other people other than you maybe who would be important people who would be making important patient safety decisions about their products? 03:14PM

A. It goes to a very small group of people.
Q. David Ciavarella is the medical director, right?
A. I don't know if he was at that time.
Q. And who is Doug Uelmen?
A. He was the vice president, I believe, of quality affairs. 03:14PM
Q. And who is John Lehmann?
A. He was a consultant.
Q. And again, what is the purpose of a health hazard evaluation? I'm not sure you told us that. What is the purpose of it? 03:14PM
A. I did tell you. It is to an assess when there is an occurrence that people want to do a deeper dive or assess from a health hazard point of view.
Q. There's concerns about the safety and the performance of the device, right? 03:15PM
A. They want to investigate what happened.
MR. LOPEZ: Your Honor, I'd like to offer Exhibit 1219 at this time. There's some redactions that have to be made but I'm not going to deal with that right now. I won't show that part of it that I know have to be redacted. 03:15PM
MR. NORTH: No objection to the admission subject to the redactions.
THE COURT: All right. 1219 is admitted.
MR. LOPEZ: Your Honor, just to be safe I'm going to ask Gay to just blow up the description of the problem which I 03:15PM

think is safe from the issue that we're talking about.

And Gay can you also just show the top part of that? Hold on one second. Yeah. You can do that. Just so the jury can see what date this is and what it is.

BY MR. LOPEZ: 03:16PM

Q. And this is an updated health hazard evaluation?

THE COURT: Do you want this displayed?

MR. LOPEZ: Yes, Your Honor. Publish to the jury, please.

THE COURT: All right. 03:16PM

BY MR. LOPEZ:

Q. So this would indicate that is an update to two prior health hazard evaluations performed for the same hazards by Dr. John Lehmann. They call this a hazard, right? Those are Bard's words? 03:16PM

A. Yes.

Q. And these HHEs were submitted as part of a remedial action plan on March 10 and April 27, 2004?

A. That's what it says.

Q. And the update includes information from all reported cases of migration of the Recovery Filter through June 29, 2004. Correct? 03:16PM

A. Yes.

Q. Now, I know that the Recovery Filter was on the market for about a year, virtually the entire year 2003. But the real 03:17PM

launch where Bard went out and they organized and they had what they called their full market launch happen in January of 2004. Isn't that true?

A. No.

Q. If there's a document that says that -- if we have two documents that say that are the documents wrong? 03:17PM

A. I don't know what documents you are speaking of. But there was no full market release of the Recovery Filter.

Q. There's never been a full market release of the Recovery Filter? 03:17PM

A. That's my understanding.

Q. Let's go to the section that I have highlighted or the description of the problem. Okay. Now, again, this is -- Dr. Ciavarella is the only doctor in Bard that is working on this health hazard. True? 03:18PM

A. I believe Dr. Lehmann did the health hazard.

Q. Dr. Ciavarella, I think, did this one if you look at the first part.

A. No, I don't agree.

Q. So it says from Dr. Ciavarella, but it's really not from Dr. Ciavarella? 03:18PM

A. The note is from Dr. Ciavarella. I think the evaluation clearly stated it's by Dr. John Lehmann.

Q. Okay. Well, that's really not that important.

The first sentence says: This HHE is an update to two 03:18PM

prior HHEs performed for the same hazard by Dr. Lehmann.

Do we really want to argue about that?

A. I'm not arguing.

Q. The most important thing is what we have on the screen right now. Wouldn't you agree from a patient safety standpoint? 03:18PM

A. I have no idea.

Q. Okay. Let's see if this will help.

This is a description of the problem. There have been 12 reports of migration of the Recovery Filter, part of the Recovery Filter system for use in the vena cava. Filter migration has been defined in the literature and for purposes of this HHE as movement of the filter of greater than two centimeters. 03:18PM

Do you see that? 03:19PM

A. Yes.

Q. And that's from the site of deployment, correct?

A. Yes.

Q. Can we give -- a lot of times we make assumptions. I didn't know what a centimeter was until not that long ago. So two centimeters, what is that like almost an inch? Eight-tenths, three-quarters of an inch? 03:19PM

A. 2.5 is an inch.

Q. So 2.5 is an inch. So two centimeters is 80 percent, if I did it right. Is that right? Yeah. It's almost 03:19PM

three-quarters, a little more than three-quarters of an inch. Right?
A. Yes.
Q. A further important distinction in the definition of migration is whether the filter alone has moved or has moved as a component of a thromboembolus. 03:19PM
Do you see that, sir?
A. Yes.
Q. In other words, there's an issue whether or not the filter is just sitting in the vena cava moved or whether it moved after it got challenged by the kind of clot that it's supposed to stop, just like what happened in Dr. Asch's study. Yes? 03:20PM
A. I don't know. Yes. It says what it says.
Q. In the first case a hazard is created by the unintended movement of the filter, in other words, the filter is just sitting there and for no apparent reason the filter dislodges and moves. Right? 03:20PM
A. Yes.
Q. In the second case, the malfunction is best understood as a limitation of the ability of the device to carry out its intended function. These limitations are spelled out in the literature and in the IFU. 03:20PM
Did I read that correctly?
A. Yes.
Q. In other words, what it's saying is that some of these 03:20PM

migrations happened when the device, which was intended to stop a clot, actually didn't stop the clot it actually dislodged the filter. Right?
A. Yes.
Q. That sounds like it might be a design issue. True? 03:21PM
A. No.
Q. You actually redesigned the Recovery Filter to be the G2 to minimize that risk, didn't you?
A. To lessen it, yes.
Q. I think you would call that a redesign. If you changed the 03:21PM filter to take care of a problem and you redesigned it to take care of the problem it was a redesign. True?
A. So first of all, it's not a problem. These are occurrences. And, yes, we always want to make our filter better. We have total product lifecycle, it's called. We take 03:21PM all of the information we have talked about today and we put that into next generation devices. So yes, our desire was to improve it.
Q. Well, sir, what I heard in the beginning of that was this was not a problem. Is that what you said? 03:21PM
A. Yes.
Q. So the migration of the Recovery -- your message to this jury is that the migration issues that were experienced by the Recovery Filter was not a problem?
A. It's not a problem like you say it. 03:22PM

Q. Well, was it a problem to the health and well-being of the people who experienced those migrations?
A. Of course.
Q. Was it a problem to the health and well-being of those people who were seriously injured by those filters when it did not perform its intended function? 03:22PM
A. It's -- yes.
Q. Well, there was a big enough problem with what happened with the Recovery Filter the company put it on hold, didn't it?
A. I don't think so, no. 03:22PM
Q. You don't remember the company putting it on hold?
A. No, but it could have. I don't remember that.
Q. And it was a big enough problem in the Asch study where it migrated four centimeters and the Board, the Ethics Board said if it happens again we're going to stop the study and Bard said 03:23PM we're going to look at the redesign. Do you remember that?
A. No. That's not true at all.
Q. Can we look at Trial Exhibit 559, please. We can take this one down subject to the redaction issue, Your Honor. I have already offered this, right? It's in evidence. 03:23PM
THE COURT: Folks, that sound is somebody's phone. Everybody pull your phone out and make sure it's either off or on airplane mode, please.
559 has been admitted.
MR. LOPEZ: It is already in? 03:23PM

THE COURT: Yes.

MR. LOPEZ: Okay.

Could you publish 559, please, to the jury?

THE COURT: Yes, you may.

BY MR. LOPEZ: 03:24PM

Q. Could I see the top section down to the device can be better understood.

Who is George Cavagnaro?

A. He was the head of marketing at Bard Peripheral Technologies. 03:24PM

Q. And Doug Uelmen?

A. He was in quality at Bard Peripheral Technologies.

Q. And we heard from Carol Vierling earlier today. She was involved in the 510(k) of the Recovery Filter, right?

A. Yes. 03:24PM

Q. And Mr. Cav -- could you pronounce his name?

A. Cavagnaro.

Q. Cavagnaro. I felt compelled to report this week's adverse event, an RNF fracture to the HPB and to our IRB. Did I read that correctly? 03:25PM

A. Yes.

Q. Doesn't it say that the IRB suspended the trial effective immediately until the nature of the problem with the device could be better understood?

A. Yes. 03:25PM

Q. And you don't recall a similar discussion taking place among you, Dr. Asch, and Dr. Kaufman that if there was one more migration after the migration happened in Patient 9 that Bard would stop the study and reevaluate the design of the device?
A. Of course I remember that. 03:25PM
Q. And that would be a wise thing to do, right? In other words, if you have one migration and you don't know why it happened, and you allowed the study to go forward because you have told all the patients in the study about it and they have agreed to go forward, if you have another migration that you 03:25PM ought to stop the study and evaluate the design. Right?
A. That's what we agreed to, yes.
Q. And but you didn't do that after Recovery was on the marketplace. You just let migrations happen time after time after time after time for two years until the G2 was ready for 03:26PM the marketplace. True?
A. No. I would not put it that way.
Q. Okay. You had -- did you ever stop selling the Recovery Filter while it was on the market and having increasing numbers of migrations until the G2 was ready to be launched on to the 03:26PM marketplace?
A. No.
Q. Did Bard tell doctors and patients that they were experiencing these migrations that were happening out in the field and that had this happened in the pilot study done in 03:26PM

Canada, that the IRB would have stopped the study and that Bard would have looked at redesigning the Recovery Filter? Did that information get shared with doctors?
A. No, just the clinical trial information was shared with doctors. 03:27PM
Q. By the way, when Janet Hudnall was out, looks like she went a lot of different places, Tennessee.
A. I don't know where she went.
Q. It's on that document.
A. That's a list of physicians. That's not necessarily where she went. 03:27PM
Q. Did she take the opportunity when she was on this G2 road show to tell doctors about this -- these two fractures and the migration in the first and only patient challenged with a clinically significant clot in the Asch study? 03:27PM
A. I have no idea.
Q. Did she take the opportunity to tell doctors that the ethics board that was monitoring that study stopped the study as a result of the two fractures in the pregnant woman?
A. I have no idea. 03:28PM
Q. Did she take the opportunity to tell these doctors that were using Recovery filters and that she wanted to convert to the G2 Filter that the reason they thought there was a fracture in Dr. Asch's study proved to be inaccurate?
A. I have no idea what Janet told the doctors. 03:28PM

Q. But Bard knew after its first fracture with a Recovery Filter and its first fracture with a G2, G2X, and its first fracture with an Eclipse Filter that it had nothing to do with the pressures and unique environment of a woman being pregnant. True? 03:28PM

A. I don't know each of those first events. I have no idea.

Q. Did Janet Hudnall advise that Dr. Asch told Bard they shouldn't market the Recovery Filter as a permanent filter until Bard did a clinical trial?

A. Did Dr. Asch tell Janet that? 03:29PM

Q. No. I'm sorry. Did Janet tell these doctors that she was visiting that they ought to -- about Dr. Asch's experience -- I'm sorry. Let me strike that.

Did Janet Hudnall tell these doctors that we saw on that priority list that Dr. Asch thought there should be a long 03:29PM term clinical trial for this device to be used as a permanent filter?

A. Again, I have no idea what Janet Hudnall told the physicians.

Q. And by the way, speaking of clinical trials, NMT actually 03:29PM had plans to do a safety clinical trial as was discussed with Dr. Asch in Europe. Right?

A. No. As I spoke of before, it was one of the things we were considering doing.

Q. At NMT there was actually a protocol for a clinical trial 03:30PM

in Europe. True.
A. There was a draft. There was never an approved protocol.
Q. Well, there were certainly some discussions and plans about doing a clinical trial. I think we saw it on one of these exhibits earlier today on the PowerPoint slide from NMT. 03:30PM
A. Yes. We were considering it.
Q. But when Bard took over NMT there was no discussion, no consideration, nothing about doing this clinical trial that was discussed while you were at NMT. True?
A. No. I don't recall that. 03:30PM
Q. There was no discussion about doing a clinical trial, right?
A. No.
Q. At Bard?
A. No. I don't know that that's true. 03:30PM
Q. Well, could you -- you just don't know?
A. That's what I said. I don't know.
Q. If there was a discussion about doing a clinical trial, they kept it from the person who knows more about filters than anybody else at the company? 03:31PM
A. No. It was 16 years ago. I don't remember every conversation.
Q. And you don't remember being asked that question two months ago?
A. No. I don't think we talked about that. 03:31PM

Q. Now, during the -- eventually the G2 was launched, right, and Bard stopped selling the Recovery Filter?
A. Yes.
Q. And the G2 was launched as a permanent filter. True?
A. Yes, at first. 03:31PM
Q. But the Recovery stayed on the market until Bard got permission from the FDA to start selling the G2 as a permanent filter. True?
A. No. It stayed on the market after G2 was on the market. Some people preferred Recovery. 03:32PM
Q. Well, no. You continued to -- well, let me ask you. Do you have a document, one document, that you can bring to court where a doctor said, I want you to continue to sell the Recovery Filter to me even though you are taking it off the market? 03:32PM
A. Yes. We have physicians requesting to keep Recovery.
Q. Now, the second question is, could you bring in another document with you where those doctors were provided with the health hazard evaluations about the Recovery Filter and everything that the company knew about the way the Recovery Filter was causing harm in patients? Can you bring that document with you to court? 03:32PM
A. Of course not. A health hazard evaluation is confidential.
Q. Could you bring with you to court any document about a doctor who said I want to continue using the Recovery Filter 03:32PM

after Bard revealed to the doctor all of its failed migration resistance testing it did after it was launched?

MR. NORTH: Objection, Your Honor. 402 and argumentative.

THE WITNESS: Of course not. 03:33PM

THE COURT: Hold on. There's an objection I'm going to sustain on relevance. I think we need to move on, Mr. Lopez.

MR. LOPEZ: Can I have Trial Exhibit 2248.

BY MR. LOPEZ: 03:33PM

Q. Just to give -- while that's coming up, to give the jury some perspective, we're in like the fall of 2005. I can't remember the exact date, September, October. Is that when the G2 started to be marketed by Bard?

A. Fall is probably as accurate as I can get, yeah. 03:33PM

Q. And it was shortly after that, and you are aware of this, that Bard started to have unexpected reports from physicians about caudal migration. Do you remember that?

A. I do.

Q. And it resulted in a health hazard evaluation in February 03:33PM of 2006, less than six months after the device was on the market. There was cause for Dr. Ciavarella to do a health hazard evaluation, correct?

A. I don't know.

Q. There was some legitimate concern about the G2 Filter and 03:34PM

its caudal migration issues, right?
A. I don't know.
Q. And did Bard, when they have issues like that, do they do what's called a DFMEA?
A. No. They do that before. 03:34PM
Q. Was one performed after the G2 Filter started experiencing an increasing number of caudal migrations after it was on the market?
A. Yes. That failure mode was added to the DFMEA.
Q. Could we have Trial Exhibit 2248 please. 03:34PM
Are you familiar with this? We talked about this document a couple months ago about the DFMEA that was conducted by Natalie Wong on the G2?
A. I don't know if she did the DFMEA, but this report, this update is by her. 03:35PM
Q. Can we go to Page 2248-20.
MR. LOPEZ: Your Honor, I'd like to offer 2248 into evidence.
THE COURT: Is there any objection?
MR. NORTH: No objection, Your Honor. 03:36PM
THE COURT: Admitted.
MR. LOPEZ: May I publish to the jury, please, Your Honor?
THE COURT: Yes.
BY MR. LOPEZ: 03:36PM

Q. Sir, you have seen this document before, right?
A. I have.
Q. Explain to the jury what this is.
A. It's a table.
Q. Okay. 03:36PM
A. Of migration, G2 caudal thresholds, and it lists the way severities are ranked. And you take severity and occurrence and then your ability to detect it and it gives you what's called a quad level. And you see in the bottom right a distribution of those numbers to obtain a certain quad. 03:37PM
And so there's a circle, with two Number 3s, which is Quad 3 and a statement that says unacceptable risk per FMEA, Type III above threshold. And then if you read further down to the bottom, because it's a Quad 3, it would require a recommended action prior to product release. But since this 03:37PM
occurrence is post-release, this is an update to a previous document, there were no controls in place to be able to detect it prior to launch.
Q. Okay.
A. So the detection is high and the quad level is high. 03:38PM
Q. What we do know from looking at this, based on the data that came in after the G2 was on the market, and based on -- this is Bard's process here that they went through, the result was an unacceptable risk Type II -- Type III, I'm sorry, above threshold for caudal migration, true? That's the result? 03:38PM

A. No. That's not the result that's the input.
Q. And it said basically what you just said at the end, is that based on this information, the product shouldn't be launched?
A. No, I didn't say that. 03:38PM
Q. What did you say, your exact words?
A. I said -- I don't know my exact words. I believe that I said we observed this issue post-market after the filter was launched, so we went back and added these occurrences to the DFMEA that was done prior to launch. And because there was no 03:39PM control in place because they were unanticipated, we had no way to reduce the quad level until we developed a test to test it and then reduce that risk.
Q. Device was already on the market, right?
A. Yes. 03:39PM
Q. And did you -- you know who Natalie Wong is?
A. Yes.
Q. And you know she was deposed. She gave a deposition in this case?
A. She's been deposed before. I don't know about this case. 03:39PM
Q. You know she gave a deposition about this exhibit that we're talking about?
A. I would assume so.
Q. And have you read her deposition about what she says about this document and the results of this document? 03:39PM

A. No. I don't think so.
Q. Have you ever talked to her about it?
A. No.
Q. Were you involved in running this test?
A. What test? 03:39PM
Q. This FMEA?
A. It's not a test.
Q. Analysis. The analysis.
A. No, I don't think I was.
Q. And Type III is what? What's a Type III? 03:40PM
A. I don't know.
Q. Type III is on the serious end of the scale, right, Type IV being worse?
A. No. I have no idea. Yes, I guess of your severity ranking column, yes. 03:40PM
Q. It's the second highest severity ranking of this analysis, right?
A. Yes.
Q. I think you said that based on this, a finding like this it needed recommended actions prior to product release, which is 03:40PM kind of silly because the product had already been released, right?
A. It's not silly, it's actually critical. But yes, in this case it was an update to a document.
Q. So if this -- if these results had come in prior to product 03:41PM

release, in other words, just like this, unacceptable risk, all these numbers, the product would not have been released until some further action had been taken. True?
A. I can't answer that yes or no.
Q. Sir, as a result of this caudal migration analysis and the complaints that were coming in, Bard had to do something, right, to fix that problem? 03:41PM
A. Again, I don't use the word "problem." They were observations that we did not anticipate.
Q. Right. So you don't think a device not staying in place, going downward and tilting and perforating and potentially fracturing as a result of that movement is a problem? 03:41PM
A. That's not what you asked me, and that's not what this is.
Q. I'm asking you a caudal migration, just saying that doesn't tell the whole story. Caudal migration carries with it some potentially real serious problems for a patient. True? 03:42PM
A. All complications carry serious risk with them as described in our IFU.
Q. Sir, I'm asking about caudal migration right now.
A. I'm telling you caudal migration and every complication have serious risks potentially. 03:42PM
Q. Let's talk about caudal migration. That was a unique problem, serious problem, with the G2 that was not really experienced to that extent with the Recovery. True?
A. I don't use the word "serious." No. That's not true. 03:42PM

Q. Now, if a device has a propensity to move downward it also has a tendency to tilt, to perforate, and to potentially, when it tilts, to really lose some efficacy. Isn't that true?
A. There's potential for all --
Q. I'm talking about migration -- 03:43PM
THE COURT: You can't talk over each other.
MR. LOPEZ: I understand.
BY MR. LOPEZ:
Q. Right now, sir, I just want you to answer my question. Caudal migration, not all complication with the filters, I'm 03:43PM talking about the complication that is described in what we have been describing right now in these documents with the G2 Filter. Caudal migration is not a desirable complication with any filter. True?
A. Yes. 03:43PM
Q. And if there are ways to stop that by redesigning the filter, in the interest of patient safety, a company ought to do that. Do you agree?
A. I don't know they can ever be stopped, but we did try and improve it. 03:43PM
Q. And when a device migrates caudally it means it's not staying where it was put. It shows some signs of instability. Would you agree.
A. Yes.
Q. And prior to the G2 being launched, did Bard ever run any 03:43PM

bench testing to see what the caudal migration results would be in comparison to, say, the Simon Nitinol Filter or other filters that were on the market?
A. No. I already described that. That's why the quad level is what it is. There was no test prior to launch. 03:44PM
Q. Now, there was a test done after the device stayed on the market and the company continued to get increasing number of reports of caudal migration. True?
A. Yes. We responsively developed a test.
Q. You did a test -- can we bring up Trial Exhibit 1578 -- 03:44PM called the Caudal Push Test, right?
A. Yes.
Q. And that was done in November of 2006. Correct?
A. I believe August, but yes.
Q. It says "dates approved" if you look down at the end of 03:44PM this document.
THE COURT: This is not in evidence.
MR. LOPEZ: Your Honor, I'd like to offer this in evidence at this time, Exhibit 1578.
MR. NORTH: No objection, Your Honor. 03:45PM
THE COURT: Admitted.
MR. LOPEZ: Publish to the jury please, Your Honor.
THE COURT: You may.
BY MR. LOPEZ:
Q. Sir, this is approved in November of 2006, right? 03:45PM

A. It's approved in November but it began in August.
Q. And this is a test that was designed to see how the G2 Filter would resist whatever pressures were causing it to caudally migrate, right?
A. It was to develop tests. 03:45PM
MR. LOPEZ: Can we go to Page 7 of 21 on this document?
BY MR. LOPEZ:
Q. This was a caudal migration test of the G2 -- okay. This was going to be a test that involved more than just the G2. It 03:46PM was going to involve the Simon Nitinol Filter, the Recovery Filter, and some of the competitor filters to the G2, correct?
A. Yes.
Q. And, by the way, are there other filters on the market that have unlimited retrievability windows in their IFUs? 03:46PM
A. I don't know what the select IFU is or the Option 1 currently.
Q. But this was a test where Bard was going to see how do they measure up in caudal migration against a number of other filters, right? 03:47PM
A. So the OptEase and the Tulip did not.
Q. So let's go to Page 11 of 21. And this is a graph showing the results of this caudal migration push test. Do you see where I am?
A. I do. 03:47PM

Q. Okay. Now the graph is hard to read, I understand. But if you look at the very bottom line, this is the average peak load. In other words, that's the amount of load to make the device move downward, right?
A. Yes. 03:47PM
Q. And the device that has the -- took the minimum amount of load to move downward was what?
A. The Greenfield.
Q. And then the next one is the G2, right?
A. Yes. 03:48PM
Q. In fact, the G2 was worse than the Recovery Filter in this test, wasn't it?
A. Yes.
Q. And it was worse than the Tulip by a long shot if you look at this graph, right? 03:48PM
A. It was worse.
Q. And the Simon Nitinol Filter, which was the predicate device to the Recovery Filter, was -- the G2 was also much worse than the Simon Nitinol Filter for caudal migration, right? 03:48PM
A. Yes.
Q. Same with O for OptEase, a competitor, the retrievable competitor of Bard's. True?
A. Yes.
Q. Now, let's go to Page 21 of 21, please. 03:48PM

By the way, while this test was going on, while the test was being developed, and during the time Bard was continuing to receive complaints of fracture, migration, perforation, and tilt, Bard continued to -- they didn't put a hold on this. They continued to market this device, right, the G2? 03:49PM

A. Yes.

Q. In fact, it was only a permanent device at the time, but Bard wanted to make it a retrievable device so it launched a retrievability study called the EVEREST study, right? 03:49PM

A. That's correct.

Q. And the conclusion here you will see of this test, this caudal push test, the push test was the most successful test method and should be used as the primary test method for evaluating the caudal migration resistance of filters in the future. The radial compression test can be used as a secondary evaluation method to further understand filter behavior under different IVC loading conditions and should be used for informational purposes only. The rolling test has limited applicability and should not be continued to be used for evaluation of caudal migration resistance. 03:49PM 03:50PM

So it determined that this was the best test at the time to measure differences in caudal migration among various devices. Right?

A. Yes. 03:50PM

Q. And it's clear that when you look at not just the graph but the numbers, in fact, can we look at 12 of 21, please. If you just look at the pure numbers, the differences are dramatic. Would you agree?
A. I can't see it. I'm sorry. 03:50PM
Q. See the G2, the mean, 23.83; the Tulip, 216.24; the Simon Nitinol Filter, 251.55; and the OptEase 309.23. That shows a significant difference in the ability of a G2 to resist caudal migration, doesn't it?
A. It does. 03:51PM
Q. And Bard continued to sell the G2 and made no changes to deal with caudal migration until the device that Bard made after Doris Jones' device. Right?
A. We did a lot of work. We did not commercialize the device until then, yes. 03:51PM
Q. So we're in 2006 where a test reveals what we have just talked about. We have a FMEA in March of 2006 where the result was unacceptable risk. You testified earlier that you were starting to receive reports of caudal migration that you weren't expecting. And Bard continued to sell a device, 03:52PM including the Eclipse, that did not fix its caudal migration problem. True?
A. Again, I don't say we have a caudal migration problem. It did not improve caudal migration resistance.
Q. It continued to have the propensity to caudally migrate at 03:52PM

rates significantly higher than even the Recovery Filter and the Simon Nitinol Filter. True?
A. It did, yes.
Q. In fact, I think I saw a document that from the standpoint of caudal migration it was 610 times more likely to caudally migrate than the Recovery Filter. Do you remember seeing that? 03:52PM
A. No.
Q. Now, after this test, the information that was coming in from the field, the FMEA of unacceptable risk, did that information together get distributed to physicians so that they could know what was going on within Bard with respect to the caudal migration of the G2? 03:53PM
A. No. They were not aware of our testing.
Q. And then when Bard went back to FDA for another 510(k) application for the hook on the G2X, it had to go through the same process as preparing, testing, and paperwork and submitting to FDA and for FDA to clear it before you could even sell it with a hook on it, right? 03:53PM
A. Of course.
Q. And you didn't take that opportunity while you had the FDA's attention to tell them that you had already determined that the G2 needed caudal hooks put on it to solve the caudal migration problem, did you? 03:53PM
A. Actually, I think we did.
Q. But you didn't make that change, did you? 03:54PM

A. We did make that change.
Q. You didn't make that change before Doris Jones got her Eclipse device, right?
A. That's true.
MR. LOPEZ: Could I have 4409, please, Trial Exhibit 4409. 03:54PM
BY MR. LOPEZ:
Q. You are familiar with this document, of course?
A. Yes. We talked about it earlier.
MR. LOPEZ: I'm going to offer this, 4409, into evidence, Your Honor. 03:55PM
MR. NORTH: No objection, Your Honor.
THE COURT: Admitted.
MR. LOPEZ: Publish to the jury, please.
THE COURT: You may. 03:55PM
BY MR. LOPEZ:
Q. Sir, what is this document?
A. It's a brochure for the G2 Filter system for permanent placement.
Q. Did the information contained on this document ever change throughout the course of the time that the G2 was being marketed by Bard? 03:55PM
A. I don't know.
Q. And could we go to the next page, please? And could we look at the section there on the right, the section above the 03:55PM

bullet points. I'm not sure the jury -- there we go.

Okay. This is Bard's marketing brochure, and this is the information that Bard approved, corporately approved to be the messaging that went out in the medical industry about its G2 Filter, correct? 03:56PM

A. Yes.

Q. It says the G2 Filter combines the best design features of Bard's existing vena cava filters. The existing vena cava filters that existed at that time at Bard would have been the Simon Nitinol Filter. Correct? 03:56PM

A. Yes. That's one.

Q. And the Recovery Filter, at least for a little while longer. Right?

A. Yes.

Q. And to create a brand new permanent filter platform taking 03:56PM strength and stability to a new level. Did I read that correctly?

A. You did.

Q. And strength again is it won't break?

A. Partially. 03:56PM

Q. And stability means it's going to stay where you put it?

A. Right.

Q. And meaning when you say a device is stable and you say you have taken it to a whole knew level, or to a new level, you are actually saying it's better than the devices you have on the 03:57PM

market -- I'm sorry -- it's better than the predecessor devices that are described here?
A. No. That's not what this says.
Q. Well, what's "to a new level"? It means better, doesn't it? 03:57PM
A. Better than Recovery.
Q. It says existing vena cava filters, doesn't it?
A. It says we took the design features of existing vena cava filters.
Q. And this is a permanent filter and the only other permanent filter that Bard was selling at the time was the Simon Nitinol Filter, right? 03:57PM
A. No. The Recovery was also a permanent filter.
Q. But the Recovery -- but again, this language after Recovery was off the market stayed in this brochure? 03:57PM
A. That's my understanding, yes.
Q. And as this brochure was on the market after the Recovery Filter was on the market, taken off the market, the only existing vena cava filter would have been the Simon Nitinol Filter. True? 03:58PM
A. Yes, but that doesn't mean we didn't take the best design features of both of them.
Q. I'm just reading what's on the document, sir.
And let's go down to the bullet points, please. Let's go to Trial Exhibit 1616, please. Let's try Trial Exhibit 03:58PM

4438. Might be a better copy of the brochure.

Okay. This is the G2 Express. What is the G2 Express?

A. It is the next generation filter from the G2.

Q. And I have always been confused. Sometimes I see G2X and I see G2 Express. Are they the same? 03:59PM

A. They are.

Q. Let's go to the next page. So this would have been the predecessor device to the Eclipse, correct?

A. Yes. 03:59PM

Q. And nothing was done to the G2 Express or the G2X to deal with its tilting or its caudal migration or perforation issues. True?

A. It didn't have tilting or caudal migration issues.

Q. Sir, I just asked you if it -- did it do anything -- let's put it -- let me ask it this way. 04:00PM

Was there anything done to the design of the G2X to help improve its performance from the standpoint of migration, perforation, fracture, or tilt?

A. Not until Meridian was launched. 04:00PM

Sorry. That's not true. Sorry. Excuse me. I said that incorrectly.

MR. LOPEZ: Your Honor, I'd like to move 4438 into evidence, please.

MR. NORTH: No objection, Your Honor. 04:00PM

THE COURT: Admitted.
MR. LOPEZ: And published to the jury, please.
THE COURT: Yes.
MR. LOPEZ: Can we go to the next page? That might be the last page of this one, right? 04:00PM
Let's go to 4409. I'm sorry 1616, the patient brochure.
THE COURT: Are you saying 1616?
MR. LOPEZ: 1616. 1616.
BY MR. LOPEZ: 04:01PM
Q. Mr. Carr, in addition to providing brochures that salespeople would give to doctors and have at hospitals and places like that, they also developed brochures or pamphlets or something to give the patients, right?
A. Sometimes. 04:01PM
Q. And this was one of those things, one of those items. A Patient Questions and Answers, right?
A. It appears to be.
Q. And the intent was to -- this was Bard's official messaging that it wanted to give to patients. Right? 04:02PM
A. It's a Q & A; no more, no less.
Q. I understand. In other words, if Bard wanted patients to have information directly from Bard, it would be contained in this Patient Questions and Answers. Right?
A. I'm sure not all information is contained in there. It is 04:02PM

a selection of questions answers.
Q. Right, the questions and answers of the information that Bard thought was the most important information, at least from Bard, that the patient ought to have about its G2 Filter. Right? 04:02PM
A. I have no idea about importance.
Q. How do these -- these are corporately approved, aren't they, before they are given to doctors to give to patients?
A. Sure.
Q. And there was also a patient brochure -- we don't have time to go through this, and we won't. But I just want to confirm that this brochure, this Q & A was intended to be handed to doctors and it was written by -- I mean handed to patients, and it was written by Bard? 04:03PM
A. I don't think it was handed to patients, no. It was more left in a lobby like you would see in your dentist office or something. 04:03PM
MR. LOPEZ: Did I move 1616, Your Honor? I'd like to move it into evidence at this time.
THE COURT: Any objection? 04:03PM
MR. NORTH: No objection, Your Honor.
THE COURT: Admitted.
MR. LOPEZ: Can we publish it to the jury, Your Honor?
THE COURT: You may.
MR. LOPEZ: If we just look at maybe the first page. 04:04PM

And then the next page. And the next page.
BY MR. LOPEZ:
Q. So, sir, this Q&A has to be a fair balance, too, doesn't it? Anything that deals with marketing or sales has to be fairly balanced. Right? 04:04PM
A. I believe so.
Q. It can't be false and misleading, right?
A. No.
Q. I mean, I'm right, right? It cannot be false and misleading? 04:04PM
A. Yes, it cannot.
Q. Trial Exhibit 4430. Ask you if you recognize this document. This is the Eclipse brochure?
A. It could be. I'd like to see the approval page.
Q. Says "final" on the top. Do you see that? 04:05PM
A. Yes.
MR. LOPEZ: I'd like to move 4430 into evidence, Your Honor.
MR. NORTH: No objection, Your Honor.
THE COURT: Admitted. 04:05PM
MR. LOPEZ: Thank you, Your Honor.
Publish 4430, please.
THE COURT: Yes.
BY MR. LOPEZ:
Q. Now, if this device -- physically as you look, the jury saw 04:05PM

this, I think, yesterday it got passed around. If you were to put this next to a G2X it would look exactly the same except this one has kind of a blue tint to it. Right?
A. Very similar.
Q. From the standpoint of the arms and the legs and the hooks it's the same as the G2 and G2X? 04:06PM
A. It is very similar.
MR. LOPEZ: Can we go to the next page, Gay, please.
BY MR. LOPEZ:
Q. And this device was meant for doctors? 04:06PM
A. I'm sorry?
Q. I'm sorry. This brochure was meant to be given to doctors by the sales force?
A. Yes, it could be.
Q. And could we go to trial Exhibit 4433, please. 04:06PM
Can you describe what's 4433?
A. It appears to be a Q&A pamphlet just like -- similar to the one we saw for G2.
Q. This is specific to the Eclipse, right?
A. Yes. 04:07PM
Q. And this is the -- and this is, again, produced by Bard. Right?
A. Yes.
Q. Everything that is contained in here is the messaging that Bard wants to put in this patient brochure, correct? 04:07PM

A. I don't see the approval page, so I don't know for sure. But if that's the case, then yes.

MR. LOPEZ: I'd like to offer 4433 into evidence at this time, Your Honor.

MR. NORTH: No objection, Your Honor. 04:07PM

THE COURT: Admitted.

MR. LOPEZ: May I publish it to the jury?

THE COURT: You may.

BY MR. LOPEZ:

Q. This has a little red stamp, "final" on it? 04:07PM

A. Yes, it does.

Q. And this actually gets folded up into like a brochure, right?

A. I believe so, yes.

Q. And I think you told us you see these in medical offices 04:08PM now where they have pamphlets and stuff that patients walk in and take one of these and read them, right?

A. They can.

MR. LOPEZ: 770, please.

BY MR. LOPEZ: 04:08PM

Q. Sir, can you see Exhibit 770? Are you familiar with this document?

A. I have probably seen it before in my deposition. I'm fairly familiar.

Q. And what is a Concept POA? 04:09PM

A. So it's a business document that describes different strategic rationales, business cases to should we do a project and what claims we would hope to get out of it; some market information; and it's really just a product opportunity assessment. 04:09PM

Q. And we haven't seen the word "Denali" before. What is Denali?

A. Denali is our current vena cava filter.

Q. If we go to -- is there any way for you to give me a date of this document? 04:10PM

A. Are you asking me?

Q. Yeah. Is there any way to date this?

A. I don't think so.

Q. If you look at the very first page -- I'm sorry. Do you see it -- well, let's look at -- 04:11PM

MR. LOPEZ: Can I move this into evidence, Your Honor? I'd like to move this into evidence at this time.

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

MR. LOPEZ: If I could publish it to the jury, please. 04:11PM

THE COURT: You may.

BY MR. LOPEZ:

Q. If you look at the very bottom of the first page that reads: In order for this project to have impact described in this POA, the filter must have no cephalad migrations unless 04:12PM

caudal migrations have been reported for G2X.

Do you see that, sir?

A. I do.

Q. The filter must have improved fracture rates comparable, if not better, tilt performance and penetration rates and continue to provide long term retrievability. 04:12PM

Do you see that, sir?

A. I do.

Q. And while this doesn't give us a date, it does tell us that while the G2X is the Bard filter that is being marketed. Would you agree with me? 04:12PM

A. No.

Q. If you look at the strategic rational value to Bard Peripheral Vascular on the first page: There is a heightened sensitivity to complications with IVC filters in the market. 04:13PM Often all the filter business in one account is lost or significantly threatened as a result of a difficult retrieval case or a complication. Improving upon the performance of the G2 and G2X filters will not only help protect current business but will re-energize the sales force to capture more share and 04:13PM help Bard take initiative in the marketplace.

Did I read that correctly?

A. You did.

Q. Does that help now convince you that this is during the G2 and G2X era at Bard? 04:13PM

A. It could be.
Q. Let's go to the next page. They are describing here, they say: The Denali Filter and it's accompanying deployment system should deliver the following. Do you see that?
A. Yes. 04:14PM
Q. And under migration, the filter should have improved caudal migration resistance and similar improved cephalad migration resistance compared to G2. Correct?
A. Yes.
Q. Is it true this is talking about the next generation of 04:14PM device that Bard is planning to design and market?
A. No.
Q. This isn't talking about the next generation beyond G2 and G2X?
A. No, because it also talks about Eclipse. 04:14PM
Q. Where is that?
A. The bottom row of that same table.
Q. The Denali deployment system color should visually differentiate the system from Eclipse and G2 filters?
A. Correct. 04:15PM
Q. Now we know the G2, the G2X, and Eclipse is on the market, right?
A. No, I don't know that they are all on the market.
Q. They are talking about improvement of the Eclipse and G2X filters? 04:15PM

A. But there's history. They may or may not be on the market.
Q. Well, whatever device is on the market, we can determine that with another witness or by this document by looking at it later. Whatever device is on the market, and whatever time period this is, Bard is talking about a filter that should have improved caudal migration resistance and similar or improved cephalad migration resistance compared to G2, correct? It's right there under migration. 04:15PM
A. Absolutely.
Q. And as far as tilt, the next filter should have improved tilt performance in comparison to the G2, correct? 04:16PM
A. Yes.
Q. And the filter should have improved fracture performance in comparison to the G2, right?
A. Yes. 04:16PM
Q. And the filter should deliver improved penetration performance in comparison to the G2, correct?
A. Yes.
Q. And then these are issues that existed in the G2, all of these things that required improvement existed in the G2 in 2006. Right? 04:16PM
A. They are not issues that were in the G2. They are observations. And this product opportunity assessment, which is a business document, wants each of those conditions to be met and why wouldn't you. 04:16PM

Q. Okay. Because improving upon the performance, if you look at Page 1 again, of the G2 and G2X filters, will not only help protect current business but will re-energize the sales force. Right?
A. Yes. 04:17PM
Q. Was the sales force in need of being re-energized?
A. Absolutely.
Q. So like the Recovery Filter, Bard learned from the clinical experience in the G2 after it was put on the market, right?
A. We always learn from our clinical experience all the time, 04:18PM yes.
Q. Well, basically, they didn't know much about its -- it had no clinical experience with the G2 before it launched, right?
A. That's true.
Q. And so what they did is they put it out there not knowing 04:18PM really how it was going to work in a human being and waited until it started getting reports of what might be wrong with the product that might require you to have to improve it?
A. Absolutely not.
Q. Well, how else could it be? You make a device, you test it 04:18PM in a laboratory, you don't put it in a human being before it's launched. True?
A. Correct.
Q. And your concept of determining whether or not it's safe is not to do a controlled monitored clinical trial where a doctor 04:19PM

is paying attention to the patient, having the patient come back in to see if the device is actually performing in the manner in which it performed in a sheep or in the laboratory, Bard's idea was to put it out in the open marketplace without any monitoring requirements or recommendations and wait for doctors who may or may not be reporting problems with the device. Is there anything inaccurate about that, sir? 04:19PM

A. Yes.

THE COURT: Go ahead and finish your answer.

THE WITNESS: Yes. We did all the appropriate testing to put that device on the market. We did all of the benchtop testing necessary to show that it was dramatic improvement to the Recovery Filter in the design criteria that we were aiming to improve, and we did that. And we submitted a 510(k) to the FDA, and they concurred that we did all the proper testing. 04:19PM 04:20PM

THE COURT: All right. We need to break at this point. I have got a 4:30 hearing. So we're going to break until tomorrow morning, Ladies and Gentlemen. We will plan on seeing you at 9:00. Please remember not to do any research or talk about the case. And we'll see you then. 04:20PM

(Jury out at 4:20 p.m.)

THE COURT: Counsel as of the end of today, plaintiff has used 11 hours and 10 minutes and defense, two hours and 53 minutes.

I want to ask a couple of questions of plaintiffs' 04:21PM

counsel about the documents we discussed this morning. I assume that's you, Mr. Combs.

MR. O'CONNOR: The summary?

THE COURT: Well, all three of the categories of documents. 04:21PM

My first question is: Tell me how it is you intend to use these documents. What's the point you are going to be making with the summary, with monthly reports, with the complaint files?

MR. O'CONNOR: Well, to establish notice, to show the defect, the design defect, to rebut the defense claim. 04:21PM

THE COURT: I didn't ask my question clearly enough.

What are you going to do with them in front of the jury?

MR. O'CONNOR: In front of the jury? 04:22PM

THE COURT: Yeah.

MR. O'CONNOR: We're going to use them to show those issues.

THE COURT: How. What are you going to do?

MR. O'CONNOR: Use them with witnesses, for example. 04:22PM

THE COURT: Give me an example. Let's say you have got the 1006 chart in front of you. I'm trying to understand how you intend to use the evidence so I can do the 403 balancing.

MR. O'CONNOR: So for example, to cross-examine their 04:22PM

witnesses on what they knew and about the complaints; that they were receiving complaints; to dispel this notion that a fracture in a pulmonary artery is not serious; that they had complaints about it; that they were aware these would fracture and migrate and go to places like the pulmonary artery which means they have to go through the heart; to show this danger of complication to overcome this contention that was given to this jury that this is not a serious injury. 04:22PM

THE COURT: Any other uses you intend to make of it?

MR. COMBS: Your Honor, a primary defense in this case, maybe the primary defense, is that Bard filters, they pass risk/benefit analysis because they have exceptionally low rates of complications. A chart of complications goes to both the quantity and the severity as direct relevance to the risk/benefit analysis. So I don't think there's any -- 04:23PM

certainly no unfair prejudice that could substantially outweigh that direct relevance to the defense in this case.

THE COURT: Let me explain why I'm asking. There are cases which have held when you are using other instances of failure in a product, if it's going to notice you can take a 04:23PM

sampling. One case said four out of 32, show those to the jury. But if you put all 32 in, it's going to give it undue weight and it will violate 403. Where the argument could be if it's going to show a product defect you could make that illustration with a subset rather than all of them. 04:24PM

I'm trying to evaluate those cases in how this evidence will be used. So I'm interested -- I don't know if you can address that specific kind of thing.

MR. COMBS: Your Honor, they have made all the filters and all the complications an issue multiple times in opening and certainly going to repeat that with multiple witnesses about their extremely low failure rates. All these failures and their severity go to rebut that, not just a sample to give some examples. 04:24PM

THE COURT: Well, hold on Mr. O'Connor. 04:24PM

Are you going to have -- are you going to use them statistically or are you going to count up the number of failures that you have in your 1006 and say this is the failure rate, for example?

MR. COMBS: I think the answer is all the above, Your Honor. I mean, we don't know exactly what they are going to say on direct and what we need to cross-examine them with. I think those are all possibilities, Your Honor. 04:25PM

MR. LOPEZ: Your Honor, could I say one thing?

THE COURT: One thing. 04:25PM

MR. LOPEZ: IFU is obviously a big defense. He displayed that in opening. And it has certain things in there about -- that describe really what happened to our client in some ways. They are certainly going to argue that. They are going to say what's the beef? 04:25PM

What we have in these files is something that you won't see in the Simon Nitinol file. And you won't see in other -- we have the MAUDE database. In other words, it's our ability to show I think Mr. Comb said it, not just the type of incident but its severity and its frequency are extremely important. See, their defense is what's the big deal? We have migration in the IFU. We have -- 04:25PM

THE COURT: I know what their defense is. I'm just trying to drill in on exactly what you intend to use it for.

MR. LOPEZ: I think there's something pretty unique and different about the Bard filters that are not part of the way they should be described in the IFU or to doctors. In other words, it's not just migration. Some of these things have, and you heard in the Booker trial and we saw in the EVEREST results, where because of caudal migration you get fracture, tilt, and perforation sometimes. There's this cascade. There's nothing in the literature that describes this. This is a unique problem with the G2 and G2X as seen in their own study. There's that chart that shows those diagrams. So unless you have the details of all that you can't develop that part of why this is not an SIR guideline case. It just talks about the fracture rate or the perforation rate. It's got its own unique problem that would reveal itself in its clinical trial. And we -- not only was it in the clinical trial -- 04:26PM 04:26PM 04:26PM 04:27PM

THE COURT: I have got about one minute before my hearing starts.

MR. LOPEZ: I'm saying there's a bunch of those in here. We've got to be able to show this is a prolific issue. It's not just caudal migration or just not fracture. This is cascade. 04:27PM

THE COURT: Mr. North, you wanted to say something on this?

MR. NORTH: I know Your Honor has to go. I just wanted to say that for the purposes they have just articulated, 04:27PM you know, we have never said they cannot or should not be able to put the number of events in. They could talk about the type of severity of these events that do occur. They can ask witnesses about that. And maybe consistent with the case we showed the Court, the *Newcastle* case, they could show a 04:27PM sampling of some of these.

But to pile on hundreds of hundreds of hundreds of these events like they are going to, I think, triggers the 403 balance.

THE COURT: Last question. Can I see the 1006 exhibit 04:28PM you are intending to use so I can actually look at it?

MR. O'CONNOR: We'll get it to you.

THE COURT: I do have -- so this is the document.

MR. O'CONNOR: We have different versions we're using today. This is the complete document. 04:28PM

THE COURT: I want to know what you want to put into evidence because I'm going to look through it and ask how much of this is cumulative, how much of this is prejudicial so I can do the 403 balance.

MS. SMITH: This is the one with all of them. 04:28PM

MR. O'CONNOR: They are copied on both sides.

THE COURT: So is this just Bard filter -- well, is this the Recovery, G2, G2X, and Eclipse?

MS. SMITH: Correct.

THE COURT: And the four complications. 04:29PM

MS. SMITH: Correct.

THE COURT: So that's what you are wanting to put into evidence.

MR. O'CONNOR: Yes, sir.

THE COURT: The other question I had for plaintiff 04:29PM is -- by the way, what's the number of this?

MS. SMITH: It's written on there, I believe 4565.

THE COURT: The other question for plaintiff is, Mr. North made an objection this morning that the monthly reports that went to management had lots of other stuff in them besides 04:29PM this information which was irrelevant and prejudicial. What is plaintiffs' response on that?

MR. LOPEZ: You mean that talks about the stents and stuff? We can take that out.

THE COURT: I don't know what it means. I assume you 04:29PM

have talked and you know what they are objecting to in the monthly reports.

MS. REED-ZAIC: At the end of the monthly reports the Bard filters are the very first section of the attachments in the monthly reports and then it continues with different Bard filters. Those can be removed. 04:30PM

THE COURT: Is that addressing your concern about the monthly reports, Mr. North? I know you have got the other objections.

MR. NORTH: Yeah. It should, Your Honor. I would need to look back at them real quickly in light of what she just said. 04:30PM

THE COURT: Am I correct that there would be nothing then in the monthly reports that wouldn't also be included in the summary in terms of filters and events? 04:30PM

MR. NORTH: No. The last three pages have the same summaries that are in 1006.

THE COURT: That's what I'm asking.

MR. NORTH: Yeah. Each monthly report has that month's incidence. 04:30PM

THE COURT: And my understanding is the plaintiff is not intending to put into evidence the actual complaint file such as those you used, Mr. O'Connor, to show where the information came from. Is that right?

MR. O'CONNOR: That's the reason we did the summary. 04:30PM

That's correct.

THE COURT: You moved two of them in today, but you are not intending to move all of the others in?

MR. O'CONNOR: No, because we believe the summary can substitute. 04:30PM

MS. REED-ZAIC: Your Honor, if I could clarify, I don't believe the global monthly report contains every single complaint for that month. It seems there are select few.

THE COURT: All right. I think I understand that.

Thank you all. See you at 8:30. 04:31PM

(Proceeding concluded at 4:31 p.m.)

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 18th day of May, 2018.

s/Laurie A. Adams
_____
Laurie A. Adams, RMR, CRR